Exhibit "2"

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Page 1
        UNITED STATES DISTRICT COURT
      SOUTHERN DISTRICT OF WEST VIRGINIA
                AT CHARLESTON
IN RE: ETHICON, INC, ) MASTER FILE REPAIR SYSTEM PRODUCTS, ) NO. 2:12-MD-02327
LIABILITY LITIGATION
                         _) MDL NO. 2327
THIS DOCUMENT RELATES TO )
THE FOLLOWING CASES IN ) JOSEPH R. GOODWIN
wave 1 of 200:
                         ) US DISTRICT JUDGE
MARIE BANKS, ET AL. V.
ETHICON, INC., ET AL
NO. 2:12-CV-01318
ROBIN BRIDGES V.
ETHICON, INC., ET AL.
NO. 2:12-CV-00651
                          ) APRIL 30, 2016
DENNIS W. DIXON, ET AL.
V. ETHICON, INC., ET AL. )
NO. 2:12-CV-01081
                         ) VIDEOTAPED DEPOSITION OF
PAULA FISK V.
                         ) DIONYSIOS K. VERONIKIS, M.D.
ETHICON, INC., ET AL.
NO. 2:12-CV-00848
SHERRY FOX, ET AL. V.
ETHICON, INC., ET AL.
NO. 2:12-CV-00878
LOUISE GRABOWSKI V.
ETHICON, INC., ET AL.
NO. 2:12-CV-00683
NANCY HOOPER, ET AL. V.
ETHICON, INC., ET AL.
NO. 2:12-CV-00493
WILMA JOHNSON V.
ETHICON, INC., ET AL.
NO. 2:11-CV-00809
LAURA WAYNICK, ET AL. V. )
ETHICON, INC., ET AL.
NO. 2:12-CV-01151
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                                                                                                   Page 4
        VIRGINIA WHITE, ET AL. V.)
 1
                                                                   APPEARANCES:
                                                         2
       ETHICON, INC., ET AL. )
                                                                BLASINGAME BURCH GARRARD ASHLEY, PC
 2
       NO. 2:12-CV-00958
                                                         3
                                                                BY: JAMES B. MATTHEWS, ESQUIRE
                                                                  jbm@bbgbalaw.com
                                                                440 College Avenue
                                                         4
 3
       JULIE WROBLE, ET AL. V. )
                                                                Athens, Georgia 30601
       ETHICON, INC., ET AL. )
                                                                (706) 354-4000
                                                         5
 4
       NO. 2:12-CV-00883
                                                         6
 5
                                                                AYLSTOCK, WITKIN, KREIS & OVERHOLTZ.
                                                         7
                                                                PLLC
             SATURDAY, APRIL 30, 2016
                                                                BY: MARY LIU, ESQUIRE
 6
                                                         8
                                                                  mliu@awkolaw.com
                                                                17 East Main Street, Suite 200
 7
                                                         9
                                                                Pensacola, Florida 32502
                                                                (850) 202-1010
 8
              Videotaped deposition of Dionysios
                                                        10
                                                                Counsel for Plaintiffs
 9
        K. Veronikis, M.D., held at the Hilton St.
                                                        11
10
       Louis – Frontenac, 1335 South Lindbergh
                                                                BRYAN CAVE, LLP
                                                        12
                                                                BY: DAN H. BALL, ESQUIRE
11
        Boulevard, Frontenac, Missouri, commencing at
                                                                  dhball@bryancave.com
12
       8:55 a.m., on the above date, before Carrie
                                                        13
                                                                  JAMES P. EMANUEL, JR., ESQUIRE
13
        A. Campbell, Registered Merit Reporter,
                                                                  James.Emanuel@bryancave.com
14
        Certified Realtime Reporter, Illinois,
                                                        14
                                                                211 North Broadway, Suite 3600
                                                                St. Louis, Missouri 63102
15
        California and Texas Certified Shorthand
                                                        15
                                                                (314) 259-2000
16
       Reporter, and Missouri Certified Court
                                                                Counsel for Defendants
17
       Reporter.
                                                        16
18
                                                        17
                                                              ALSO PRESENT VIA TELEPHONE:
                                                                Mark Mueller, Mueller Law Office
19
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21
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22
                                                        21
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23
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2.4
                                          Page 3
                                                                                                   Page 5
 1
                INDEX
                                                                     DIONYSIOS K. VERONIKIS, M.D.,
 2
                          PAGE
                                                          2
                                                                of lawful age, having been first duly sworn
      APPEARANCES..... 4
 3
                                                          3
                                                                to tell the truth, the whole truth and
 4
      EXAMINATIONS
                                                          4
                                                                nothing but the truth, deposes and says on
 5
       BY MR. BALL..... 5
                                                          5
                                                                behalf of the Defendants, as follows:
 6
       BY MR. MATTHEWS...... 293
                                                          6
 7
       BY MR. BALL.....295
 8
                                                          7
                                                                        DIRECT EXAMINATION
 9
               EXHIBITS
                                                          8
                                                                QUESTIONS BY MR. BALL:
10
       No. Description
                                 Page
                                                          9
                                                                    Q. Would you tell us your name,
11
      1 Notice of deposition
                                                        10
                                                                please?
12
         Rule 26 Expert Report of Dr.
                                       13
                                                        11
                                                                    A. Dionysios Veronikis,
         Dionysios K. Veronikis TVT
                                                        12
                                                                D-i-o-n-y-s-i-o-s, V-e-r-o-n-i-k-i-s.
13
         Rule 26 Expert Report of Dr.
                                       13
                                                        13
                                                                    Q. Dr. Veronikis, my name is Dan
14
         Dionysios K. Veronikis Gynecare PS
                                                        14
                                                                Ball, and I represent Ethicon. And I'm going
15
         Thumb nail drive of documents
                                                        15
                                                                to be asking you some questions about the two
16
         CD of documents
                                                        16
                                                                reports you've submitted in the federal court
17
                                                        17
                                                                litigation involving TVT® and involving
18
      CERTIFICATE...... 296
                                                                Gynemesh® PS.
                                                        18
      19
      ACKNOWLEDGMENT OF DEPONENT...... 299
                                                        19
                                                                        You understand that?
      LAWYER'S NOTES...... 300
                                                        20
                                                                    A. Yes.
20
                                                        21
                                                                        (Veronikis Exhibit 1 marked for
21
                                                        22
                                                                   identification.)
22
                                                        23
                                                                QUESTIONS BY MR. BALL:
23
                                                        24
                                                                    Q. So the first thing I'm going to
24
```

2 (Pages 2 to 5)

	Page 6		Page 8
1	do is mark as Exhibit 1 to your deposition	1	CD which is?
2	and ask you to just briefly take a look at	2	MR. MATTHEWS: His reports for
3	that.	3	each product and the footnotes for
4	A. Yes.	4	each product. The documents that
5	Q. Exhibit 1 is the notice to take	5	reference that are referenced in
6	this deposition, right?	6	the footnotes.
7	A. Yes.	7	MR. BALL: Great. Thank you
8	Q. And have you seen this before?	8	for that.
9	A. Yes, sir. It was e-mailed to	9	QUESTIONS BY MR. BALL:
10	me by Mr. Matthews.	10	Q. Now, have you charged for your
11	Q. And there's an attachment to	11	services in this case?
12	that asking you to bring various things to	12	A. Not yet.
13	the deposition.	13	Q. Okay. Do you intend to?
14	Did you get a chance to look at	14	A. Yes.
15	that.	15	Q. Okay. And what will be the
16	A. I did, and I spoke with	16	basis for your charges?
17	Mr. Matthews, and he said he would bring	17	How will those be calculated?
18	everything.	18	A. It's an hourly rate.
19	Q. Now, so do you have anything, I	19	Q. And what is that?
20	guess, Mr. Matthews to produce with respect	20	A. It's a thousand dollars an
21	to the depo notice?	21	hour.
22	MR. MATTHEWS: You want to	22	Q. And do you have an estimate as
23	well, those boxes there contain the	23	to how many hours you spent coming into the
24	documents that are referenced as	24	start of this deposition?
			•
	Page 7		Page 9
1	footnotes in his reports in both of	1	A. Could you just for
2	them. This thumb drive contains	2	preparation of this deposition?
3	everything that he was sent and	3	Q. Yeah, that's fair. I'm going
4	reviewed.	4	to ask a series of them so we'll start off.
5	MR. BALL: Okay.	5	First of all, to prepare the
6	MR. MATTHEWS: There's if	6	two reports that we're going to be talking
7	you don't want to take the boxes or	7	about here today?
8	mark them as exhibits, there's a	8	A. So it's about 50 hours.
9	everything in those boxes is on a CD	9	Q. And any other work you've done
10	that I also brought with ma	10	in preparation for this deposition?
	that I also brought with me.		= =
11	MR. BALL: So I think what I'll	11	A. I reviewed everything that they
11 12	MR. BALL: So I think what I'll do is mark the thumb drive and the	12	A. I reviewed everything that they had sent me, and it was a ton of stuff.
11 12 13	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We	12 13	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was
11 12 13 14	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them.	12 13 14	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that?
11 12 13 14 15	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I	12 13 14 15	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the
11 12 13 14 15	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient	12 13 14 15 16	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet.
11 12 13 14 15 16 17	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way.	12 13 14 15 16 17	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with
11 12 13 14 15 16 17 18	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5	12 13 14 15 16 17 18	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would
11 12 13 14 15 16 17 18 19	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.)	12 13 14 15 16 17 18 19	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the
11 12 13 14 15 16 17 18 19 20	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.) MR. BALL: Exhibit 4 is a thumb	12 13 14 15 16 17 18 19 20	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours?
11 12 13 14 15 16 17 18 19 20 21	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.) MR. BALL: Exhibit 4 is a thumb drive which is?	12 13 14 15 16 17 18 19 20 21	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours? A. Yes.
11 12 13 14 15 16 17 18 19 20 21 22	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.) MR. BALL: Exhibit 4 is a thumb drive which is? MR. MATTHEWS: All of his	12 13 14 15 16 17 18 19 20 21 22	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours? A. Yes. Q. And what is your charge for
11 12 13 14 15 16 17 18 19 20 21 22 23	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.) MR. BALL: Exhibit 4 is a thumb drive which is? MR. MATTHEWS: All of his reference materials.	12 13 14 15 16 17 18 19 20 21 22 23	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours? A. Yes. Q. And what is your charge for deposition?
11 12 13 14 15 16 17 18 19 20 21 22	MR. BALL: So I think what I'll do is mark the thumb drive and the or I don't even need to mark them. We can just yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way. (Veronikis Exhibits 4 and 5 marked for identification.) MR. BALL: Exhibit 4 is a thumb drive which is? MR. MATTHEWS: All of his	12 13 14 15 16 17 18 19 20 21 22	A. I reviewed everything that they had sent me, and it was a ton of stuff. Q. And about how many hours was that? A. 300. 350. I didn't add up the numbers just yet. Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours? A. Yes. Q. And what is your charge for

1	Page 10		Page 12
_	10,000 for entire day.	1	Now, on this notice
2	Q. How about two-thirds of a day,	2	Q. Yeah.
3	what is that?	3	A there's only one patient
4	Is it done on some hourly basis	4	that I've seen from this notice.
5	or	5	Q. And I wasn't just limiting to
6	A. If it's an hour and a half or	6	that notice.
7	two hours sometimes, I'll, just to be fair,	7	A. Okay.
8	that's what it is. If it takes a half day or	8	Q. I was saying in general you've
9	a full day, I try to be fair and consistent.	9	seen about ten patients, Ethicon litigation
10	Q. And is that what your charge	10	patients?
11	would be if you ever appeared for trial would	11	A. Yes.
12	be \$10,000 a day?	12	Q. And they've been about 10 or
13	A. Yes.	13	\$12,000 per patient to do an examination and
14	Q. Does that include if you had	14	a report?
15	to travel to West Virginia, would it be	15	A. Yes.
16	\$10,000 the day you travel over there?	16	Q. And review the records?
17	A. It would be traveling expenses	17	A. Yes.
18	and my day there.	18	Q. And then in those cases, you
19	Q. So let's say you were going to	19	either have or in the process of giving
20	testify on a Tuesday and you went over on a	20	depositions on those?
21	Monday, would it be \$10,000 for Monday and	21	A. I've been deposed on one
22	10,000 for Tuesday?	22	patient.
23	A. No.	23	Q. Okay. And that's a \$6,000 per
24	Q. What would the Monday be?	24	half day charge for that?
24	Q. What would the Monday be:	24	han day charge for that:
	Page 11		Page 13
1	A. My travel expenses.	1	A 771 . 1 . 1 . 111
2		_	A. That was only two hours so I'll
	Q. Okay. You wouldn't charge for	2	3
3	Q. Okay. You wouldn't charge for your time in traveling?		probably just submit for two hours. I think
	Q. Okay. You wouldn't charge for your time in traveling?A. No.	2	probably just submit for two hours. I think the Attorney Emanuel was there for that.
3	your time in traveling? A. No.	2 3	probably just submit for two hours. I think the Attorney Emanuel was there for that.
3 4	your time in traveling? A. No. Q. Okay. Now, you also served as	2 3 4	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars?
3 4 5	your time in traveling? A. No.	2 3 4 5	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right.
3 4 5 6 7	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes.	2 3 4 5 6 7	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two
3 4 5 6	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving	2 3 4 5 6	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here
3 4 5 6 7 8	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon?	2 3 4 5 6 7 8	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen
3 4 5 6 7 8 9	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for	2 3 4 5 6 7 8	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here
3 4 5 6 7 8 9	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews?	2 3 4 5 6 7 8 9	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work
3 4 5 6 7 8 9 10	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone.	2 3 4 5 6 7 8 9 10	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No.
3 4 5 6 7 8 9 10 11 12	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten.	2 3 4 5 6 7 8 9 10 11 12	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been
3 4 5 6 7 8 9 10 11 12 13	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone.	2 3 4 5 6 7 8 9 10 11 12 13	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases
3 4 5 6 7 8 9 10 11 12 13 14	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been
3 4 5 6 7 8 9 10 11 12 13 14 15	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers? A. No.
3 4 5 6 7 8 9 10 11 12 13 14 15	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients? A. Yes. Q. Okay. And do you have an estimate as to what your average billings	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers? A. No. Q. Have you ever been engaged to
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients? A. Yes. Q. Okay. And do you have an estimate as to what your average billings were per case on each one of those?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers? A. No. Q. Have you ever been engaged to testify by a mesh manufacturer or serve as an
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients? A. Yes. Q. Okay. And do you have an estimate as to what your average billings were per case on each one of those? A. It depends on the number of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers? A. No. Q. Have you ever been engaged to testify by a mesh manufacturer or serve as an expert by a mesh manufacturer?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	your time in traveling? A. No. Q. Okay. Now, you also served as an expert witness on individual cases? A. Yes. Q. How many of those involving Ethicon? A. In the patients I examined for everyone who sent or just Mr. Matthews? Q. Everyone. A. Maybe ten. Q. Ten patients? A. Yes. Q. Okay. And do you have an estimate as to what your average billings were per case on each one of those? A. It depends on the number of records and the time. It varies from 7,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	probably just submit for two hours. I think the Attorney Emanuel was there for that. Q. So that would be a couple thousand dollars? A. Right. Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon? A. No. Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers? A. No. Q. Have you ever been engaged to testify by a mesh manufacturer or serve as an expert by a mesh manufacturer? A. No.
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4 (Pages 10 to 13)

2 report relating to 3 is that right? 4 A. Yes. 5 Q. And F. report and mate 7 report in this lit 8 Gynemesh® P.S.	erials that accompany the to TVT® in this litigation;	1 2	playing. MR. BALL: James, can you just
2 report relating to 3 is that right? 4 A. Yes. 5 Q. And F. report and mate 7 report in this lit 8 Gynemesh® P.S.			
3 is that right? 4 A. Yes. 5 Q. And E 6 report and mate 7 report in this lit 8 Gynemesh® PS			max. Dall. James, can you just
4 A. Yes. 5 Q. And F 6 report and mate 7 report in this lit 8 Gynemesh® PS		3	send the few people, whoever you
6 report and mate 7 report in this lit 8 Gynemesh® PS		4	wish and I'm not questioning, I'm
6 report and mate 7 report in this lit 8 Gynemesh® PS	Exhibit 3 is a copy of the	5	just saying I got different
7 report in this lit8 Gynemesh® PS	erials that accompanied the	6	information and I just want to see
8 Gynemesh® PS	igation related to	7	what they said and see
	=	8	MR. MATTHEWS: It was an
9 A. Yes.	•	9	agreement between Tom Cartmell and
10 Q. Now,	pursuant to the court	10	Brian Aylstock and Dave Thomas. And
11 rules, do Exhib	its 2 and 3 contain all of	11	that's the way every deposition has
12 your opinions a	nd bases for those opinions	12	been done so far.
that you intend	to express in this	13	MR. BALL: I'm not disputing.
14 litigation?	_	14	I just want to
15 A. Up to	this point, yes.	15	MR. MATTHEWS: I understand.
	ATTHEWS: So we're on the	16	That's fine.
same page,	some people have been doing	17	MR. BALL: trust and verify.
18 depositions	when the deponent has	18	MR. MATTHEWS: I'm just trying
_	eports by doing the	19	to get out of here earlier.
	on one report and then a	20	QUESTIONS BY MR. BALL:
-	position on the second	21	Q. All right. Now, what I would
	ne people have just taken	22	like to do, first of all, is talk about what
	o do kind of a	23	your practice is and has been the last
24 combination	n.	24	several years.
	Page 15		Page 17
	ALL: I thought it was	1	All right?
2 six.		2	A. Sure.
	ATTHEWS: It's five on the	3	Q. Do you perform surgery for
· · · · · · · · · · · · · · · · · · ·	the second.	4	stress urinary incontinence?
	U: Three on the first.	5	A. Yes, sir.
	ATTHEWS: I mean, three on	6	Q. Okay. SUI?
	o on the second.	7	A. Yes.
	ALL: I was told three and	8	Q. Okay. Do you perform surgery
	se there's two calm	9	for prolapse?
down.	A TOTAL TOTAL CO.	10	A. Yes.
	ATTHEWS: It's three and	11	Q. Anterior, posterior, apical?
	don't care if you do five	12	A. Yes.
	ombine them.	13	Q. And of those two types of
	ALL: I'm going to do five	14	surgeries, which do you do more?
	ombine them because I'm not	15	A. It's hard to say. You get
	h to draw that line so	16	patients that present with predominantly
17 precisely.	ATTITUTE IN 14	17	prolapse symptoms and when you reduce that
	ATTHEWS: Fine with me.	18	prolapse, they also have incontinence. You
	ALL: Having said that, I	19	have other patients that present with a
	ind of go through mostly	20	primary complaint of incontinence, you
	and then mostly Gynemesh®	21	examine them and they have other defects.
PS stuff.	ATTHEWS. Daniel	22	So you end up doing a lot. It
	ATTHEWS: Doesn't matter	23 24	might be fair to say, I don't know, 50/50.
as long as I	know what game we're	4	Q. Okay. Do you also do surgery

	Page 18		Page 20
1	to deal with issues related to mesh products	1	are for SUI.
2	that have already been implanted?	2	Q. Vast majority of the removals?
3	A. Unfortunately.	3	A. Yes.
4	Q. Okay. How does that fall	4	Q. Okay. Now, one of the products
5	which is more common, that surgery or the	5	that we're going to be talking about here
6	original surgeries that you do for prolapse	6	today is a TVT® device, true?
7	or SUI?	7	A. Yes.
8	A. So I've limited the patients	8	Q. Made by Ethicon, true?
9	that I see with mesh complications and I try	9	A. Yes.
10	to balance that between 50 percent mesh	10	Q. And have you ever implanted a
11	complications and 50 percent primary	11	TVT®?
12	patients.	12	A. I think I did it once or twice.
13	Q. Has that been the case for the	13	Q. Okay. When?
14	past several years, or have the percentages	14	A. When it first came out.
15	differed?	15	Q. Do you have a specific
16	A. I've actually dialed it down a	16	recollection of that or not?
17	little bit.	17	A. I have a specific recollection
18	Q. Dialed what down?	18	because Hattie Loggie, who was the local rep,
19	A. The number of patients that I	19	was very interested in obtaining my business
20	will see with mesh complications.	20	since I do a large volume and that would be
21	Q. Okay. What did it use to be	21	good for her.
22	percentagewise?	22	I know there were discussions
23	A. Oh, at one point it was 60,	23	after that they kept trying to get me to use
24	70 percent, and I'm in a training program and	24	it, but I was not happy with the approach to
	, o percent, and 1 m m m manning program and		in, out I was not happy with the approach to
	Page 19		Page 21
			10.50 21
1	by doing more of the complicated mesh	1	implant the product or the product itself.
2	removals, the residents in training weren't	1 2	implant the product or the product itself. So I kind of got pressured to try one because
2 3	removals, the residents in training weren't getting enough of the educational-type of		implant the product or the product itself.
2 3 4	removals, the residents in training weren't getting enough of the educational-type of procedures that they need to participate in.	2	implant the product or the product itself. So I kind of got pressured to try one because they said try one, and then I tried a second one, and I didn't do anymore.
2 3 4 5	removals, the residents in training weren't getting enough of the educational-type of procedures that they need to participate in. It created some grief so I dialed it back a	2 3	implant the product or the product itself. So I kind of got pressured to try one because they said try one, and then I tried a second
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	removals, the residents in training weren't getting enough of the educational-type of procedures that they need to participate in. It created some grief so I dialed it back a little bit. Q. And how long ago was it that it was 60 to 70 percent? A. 18 months ago. Q. So what is the what does that work out to annually if it's 50 percent, let's say, how many mesh complication surgeries per year? A. So in 2015, I removed 296 implants. I did a total of 605 surgeries. Q. Very precise. The mesh implants that you removed, let's use last year, how many of those were for SUI as opposed to for prolapse? A. I have that number, but I don't have it off the top of my head. I looked at	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	implant the product or the product itself. So I kind of got pressured to try one because they said try one, and then I tried a second one, and I didn't do anymore. Q. And when was that? A. Early when it first came out, very early. Ballpark, 2000 to 2003. Q. That time period? A. Yes, sir. Q. What was it about the approach you said the approach and the product, I think that's the word you used? A. Yes. Q. What was it about that A. Well Q that you were dissatisfied with? A. Yes. I was very used to doing synthetic slings, and being trained as a vaginal surgeon, I had ideas of what a safe, effective surgery should be. When I looked at the IFU and the videos for performing the

Page 22 Page 24 1 opinion, safe. 1 unsafe. It yielded a high risk of a bladder 2 In the ones I did perform, I 2 puncture and injury. So I didn't follow 3 3 did not follow Ethicon's recommendations. I those. 4 4 did what I normally do for slings and used Q. Did you use the -- the 5 their product. 5 procedure you did use, did you use the trocar Q. What was it about the procedure 6 6 that came with the sling? 7 7 A. I used the trocar, but I didn't that you considered to be unsafe? 8 8 A. The procedure was supposed to use the handle. 9 start with a 1.5 centimeter incision, 1 9 Q. Okay. And just briefly how did your approach differ from what was 10 10 centimeter from the urethra medias. That 11 area of the anatomy immunologically develops 11 recommended in the IFU? 12 from the sinovaginal bulbs, and it's fused so 12 A. Sure. you can't really gauge the depth of 13 13 So I started my incision about 14 dissection accurately. And it's a 14 the midanterior vaginal wall. I identified 15 curvilinear structure. It's a tube. So you 15 the vesicovaginal space. What that had me do 16 really need to separate that structure much 16 is it identified the blood supply and the 17 17 thickness of the vaginal wall. I carry that more precisely. dissection all the way to the urethra medias. 18 So the way that the 18 19 instructions were was to make an incision and 19 I separated the vaginal wall from the 20 20 urethra. I then pierced the urogenital then make a half-centimeter blunt dissection, 21 21 and at the time they had the 5-millimeter diaphragm, created a much larger than 22 22 1-centimeter opening. I opened the trocar, and you're trying to take a round 23 structure, a trocar, and compress it between 23 retropubic space. 24 24 the flap that you created and then they had I developed an instrument that Page 23 Page 25 1 the device inside, the guide wire, which 1 allows me to get on the side of the bladder 2 really doesn't do anything if you really 2 between the obturator internus muscles and 3 think about it -- but I don't want to get 3 the bladder sidewall and push that bladder ahead of myself. 4 wall over. Holding in that blunt retractor, 4 5 5 So it was a 5-millimeter sort of like a trocar but it's blunt, so when 6 6 you push it, it won't poke a hole. I was trocar, supposed to make a 5-millimeter 7 incision and tunnel it a little bit. I had 7 able to move the bladder and all of the 8 8 read Ulmsten's original report and in his structures to the posterior aspect of the 9 9 original report you were supposed -- he said abdominal wall. Then touching that blunt 10 10 make .5 to 1 centimeter. So the difficulty I retractor with a sharp trocar, the only thing 11 had was with the pressure that was required 11 I pierced was the rectus muscles. I did that 12 12 to pass the trocar, the snug fit between the on both sides. 13 vaginal wall and the urethra, which was a 13 Q. Which is what you wanted to 14 pierce? 14 tubular structure, not moving the lateral 15 15 bladder side wall. The guide wire would be A. Yes. 16 Okay. Now, the instrumentation 16 like taking a pen and putting it into a water 17 bottle; it's not going to move the sides in. 17 and the procedure that was in the IFU and 18 with the TVT® back 15 years or so ago when 18 And the safety aspects of doing a sling is to 19 you did this, is that the same -- has that 19 move the paravaginal retropubic space and 20 open that up and move the bladder medially so 20 before changed? 21 Has Ethicon ever changed either 21 when you pass that trocar, you're literally 22 for the TVT®, either its instrument or its 22 passing it through an open space. 23 recommended procedure? 23 The technique that was 24 described and asked me to do I thought it was 24 A. I'm going to ask a question.

	Page 26		Page 28
1	Q. Sure.	1	used to use BARD Uretex.
2	A. You're assuming we're talking	2	Q. So Caldera is a company?
3	about retropubic slings?	3	A. Yes, sir.
4	Q. Yes. That's all your report	4	Q. Does it have a brand within
5	deals with.	5	that company?
6	A. Yes, I didn't comment on TVT®	6	A. I think the implant is called
7	Exact, but they did	7	Desara.
8	Q. But your report is only about	8	Q. And how long have you been
9	the TVT® retropubic sling?	9	using that?
10	A. Yes, sir.	10	A. Since 2010.
11	Q. That's all I am talking about	11	Q. Does that come with
12	here. And if I ask about something else,	12	instrumentation?
13	I'll	13	A. Instrumentation is provided,
14	A. Okay. They did change it and	14	yes.
15	call it TVT® Exact where they changed the	15	Q. Do you use it?
16	trocar a little bit and put a plastic sheath	16	A. I do not.
17	on the end of the mesh, but the tenets of the	17	Q. And does it come with an IFU?
18	procedure pretty much stayed the same.	18	A. It does.
19	Q. So the TVT® even through the	19	Q. Does the IFU give a recommended
20	TVT® Exact, both the instrument and the	20	technique?
21	recommended technique have remained	21	A. It does.
22	essentially the same?	22	Q. Do you follow that technique?
23	A. They have.	23	A. I do not.
24	And what it does is it takes a	24	Q. Why do you not use the
	Page 27		Page 29
1	1-centimeter mesh and upon implantation, it	1	instrumentation that comes with the Desara?
2	forces it to fold in that 5-millimeter	2	A. It's not designed quite right.
3	tunnel.	3	Q. Okay. Do you believe it is, at
4	Q. Do you have more criticism of	4	least to some degree, unsafe, use of that
5	the TVT® with respect to the procedure and	5	instrumentation?
6	the trocar instrumentation that's being used	6	A. I've never used it.
7	or with respect to the mesh itself?	7	Q. Okay. And you don't use it
8	A. I have criticisms of the entire	8	because you think it might be unsafe?
9	kit, and that kit consists of the delivery	9	A. I don't use it because I
10	system and the mesh.	10	designed my own trocar that allows me more
11	Q. I know that.	11	precision in how to handle it.
12	What I asked you is do you have	12	The TVT® trocar had a handle on
13	criticism more of one than the other, the	13	it. I didn't use the handle, but at least
14	technique and the instrumentation on the one	14	that handle was detachable. The Desara
15	hand versus the mesh?	15	handles have a nondetachable handle. It
16	A. I have criticism of both. I	16	gives you too much torque. So I developed a
17	don't know which one would be more because	17	trocar that does that limits how much
18	they're sort of together. You really can't	18	torque you apply. Makes it safer.
19	isolate the one from the other.	19	Q. Is that your own special
20	Q. Now, what do you use	20 21	does it have a name? A. No.
21	polypropylene slings today for SUI?	21	
22	A. I do.	23	Q. Okay. Is it commercially available?
23	Q. Okay. What product?		
24	A. I'm currently use Caldera. I	24	A. It can be but, no.

	Page 30		Page 32
1	Q. What do you mean?	1	A. Yes.
2	A. Well, if someone wanted it, I	2	Q. And you did not use that
3	would make one for them.	3	technique?
4	Q. But you're not trying to	4	A. I did not.
5	commercially develop them?	5	Q. Okay. What was it about the
6	A. Oh, no. No.	6	Uretex instrument that made it acceptable to
7	Q. Why don't you use the Desara	7	use and so you didn't use your own?
8	technique?	8	A. It allowed me to pass the
9	A. All of the techniques are	9	trocar without the sling. So I was able to
10	pretty much the same for all the slings.	10	create my exposure, dissect the vaginal wall,
11	They all want you to do it kind of the same	11	open it the way I like, dissect the
12	way.	12	retropubic space, pass the trocar, leave
13	Q. The way you described on the	13	at that point it was a little plastic tube
14	TVT®?	14	leave a little blue tube in position, remove
15	A. Yes, sir.	15	the trocar, do the other side, not bring the
16	Q. Okay. And for the reasons	16	sling into the field at all because it is
17	you've described, you don't find that	17	sort of a contaminated area.
18	acceptable and you use the technique that you	18	So it allowed me to not bring
19	described earlier?	19	the mesh on to the field until I was ready to
20	A. Yes.	20	implant it. Because if you have a bladder
21	Furthermore, the Desara product	21	puncture, you had bleeding, the patient was
22	doesn't have a tubular attachment to it so it	22	stooling on the table, you know, you had
23	allows me to tailor the surgery to my own	23	complete control of it, which is what I'm
24	preferences as opposed to being confined.	24	able to do with Desara, which is what I did
	r · · · · · · · · · · · · · · · · · · ·		
	Page 31		Page 33
1	It's not as easy to do that	1	for my first sling.
2	with some of the other slines		
	with some of the other slings.	2	So the slings I have used have
3	Q. Including the TVT®?	2	So the slings I have used have been an Ethicon Mersilene from '94 to 2003
3 4	Q. Including the TVT®?A. Yes.		
3	Q. Including the TVT®?A. Yes.Q. You said you used a BARD	3	been an Ethicon Mersilene from '94 to 2003
3 4	Q. Including the TVT®?A. Yes.	3 4	been an Ethicon Mersilene from '94 to 2003 Q. Did you think that was a safe
3 4 5	 Q. Including the TVT®? A. Yes. Q. You said you used a BARD product before the Desara? A. Yes. 	3 4 5	been an Ethicon Mersilene from '94 to 2003 Q. Did you think that was a safe product?
3 4 5 6 7 8	 Q. Including the TVT®? A. Yes. Q. You said you used a BARD product before the Desara? A. Yes. Q. And what was the name of that? 	3 4 5 6	been an Ethicon Mersilene from '94 to 2003 Q. Did you think that was a safe product? A. I did at the time. Q. Do you today? A. Its properties as an implant
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	Page 34		Page 36
1	terephthalate, which is what Mersilene was,	1	Mersilenes to clarify. There's Mersilene
2	may be degrading a little bit. I certainly	2	mesh, which comes in a sheet which is about
3	didn't want that.	3	10 inches by 10 inches, and there's Mersilene
4	It was touted that	4	ribbon, which is used for cerclage, which is
5	polypropylene was the next great material.	5	actually one of the first uses of a sling was
6	It was less invasive, and I developed a	6	by Tiffany Williams and TeLinde in '62. It
7	technique that was very similar to the	7	was a very similar TVT®, small needles, and
8	Mersilene placement, which I was very	8	they used it for cerclage
9	comfortable with, which I knew what the	9	Q. Which did you use?
10	outcomes were, and went to Uretex.	10	A. The Mersilene mesh.
11		11	
12	- · · · · · · · · · · · · · · · · · · ·	12	
	Mersilene, and then 2000 to 2010 was Uretex,		A. Yes, sir. And I would cut it,
13	or did I miss anything in between?	13	like you said.
14	A. Close.	14	Q. Okay. And then from '03 to
15	So '94 to about 2003.	15	'10, you used the BARD Uretex until it wasn't
16	Q. Okay. Was Mersilene?	16	sold anymore, and then from '10 forward the
17	A. Mersilene.	17	Desara?
18	I also didn't like the TVT®. I	18	A. Yes.
19	was kind of spoiled. When I handled the	19	Q. Now, do you know or have any
20	Mersilene, it didn't fray, it didn't fall	20	opinion today as to what else is out
21	apart. I could manipulate the edges. I	21	there?
22	could suture the edges. There was things	22	There's the TVT®?
23	that I could do to it that I still do	23	A. Yes.
24	surgically that I could not do with the TVT®.	24	Q. And the various iterations of
	Page 35		Page 37
1	One of the things with	1	the TVT®?
2	Mersilene is that it has a bias. So the	2	A. Yes.
3	first thing I did, knowing that, and I didn't	3	Q. And then there's Desara?
4	know any better, was I pulled on the TVT® and	4	A. That's Desara.
5	it frayed.	5	Q. What else?
6	Q. Is Mersilene still sold for	6	A. There's Advantage and Advantage
7	sling repairs?	7	Fit by Boston Scientific.
8	A. It was never really sold for	8	Q. Okay.
9	sling repairs. It was sold as a product that	9	A. There was a line by BARD.
10	you used as a surgeon as you saw fit.	10	There is the Supris by Coloplast. And I'm
11	Q. Okay. Did you have to cut it	11	not sure if I'm missing anyone.
12	for a particular surgery?	12	Q. Have you used any of those
13	A. Yes.	13	other ones that you just mentioned, the
14	Q. Okay. Did it come with its own	14	Coloplast, the BARD Align or the Boston
15	instruments?	15	Scientific one?
16	A. It did not.	16	A. I used the Align when
17	Q. Okay. So just so I've got the	17	because BARD was the import of Sofradim from
18	timeline.	18	France.
19	'94 to 2003, the Mersilene	19	When they were no longer able
20	product from Ethicon?	20	to get it, they said they were coming out
21	•	21	with a sling. I tried it. I did not like
21		22	_
	Q. Which was called what, just called Mersilene?	23	the characteristics. I confirmed that sling was didn't have the same characteristics
23			
24	A. Yeah, just well, there's two	24	as the Uretex. When I would operate at a

	Page 38		Page 40
1	certain hospital, the only product they had	1	Q. And have you ever had to remove
2	was Boston Scientific so they would not get	2	all or a portion of a sling implanted by you?
3	me the Desara. So on a few cases I had to	3	A. I release slings for some
4	use the Boston Scientific product.	4	voiding difficulty. I cut them in the
5	Q. What hospital was that?	5	middle.
6	A. St. Anthony's.	6	Q. Have you ever had to remove a
7	Q. Okay.	7	sling or a portion of a sling?
8	A. I stopped going there because	8	A. I've reviewed
9	of that.	9	Q. Implanted by you?
10	Q. Okay. Did you think that was	10	A. Yes, I've removed a sling I've
11	an acceptable product or not?	11	implanted.
12	A. Very heavy. It had the same	12	Q. How many?
13	limitations as the TVT® Exact. It's a flat,	13	A. To my knowledge, one.
14	1-centimeter piece of mesh rolled and	14	Now, that was a lady that had a
15	attached to almost like a straw where you put	15	previous TVT®, had a failure. I got a sling,
16	the trocar through there.	16	a second sling, and was still having
17	Again, I didn't follow the	17	incontinence. So what I did is I removed
18	manufacturer's instructions.	18	both the TVT® and my sling to start over.
19		19	· ·
20	Q. All right. Now, of those that have been on the market the last several	20	Q. Is it your testimony that the
21		21	TVT® procedure kit, product, is so unsafe
22	years, do you have any opinion or impression	22	that it never should be on the market?
23	as to which has been most commonly used by		A. I think the risks far outweigh
24	surgeons for SUI? A. I don't.	23	the benefits.
24	A. I don't.	24	Q. So it never should have been
	Page 39		Page 41
1	Q. So you don't know which one is	1	sold?
2	the biggest seller, so to speak?		
	the diggest seller, so to speak?	2	A. No.
3	A. No, but I see how many of each	2 3	A. No.Q. You agree with that?
3 4			
	A. No, but I see how many of each	3	Q. You agree with that?
4	A. No, but I see how many of each I remove, and it's the TVT® is maybe a	3 4	Q. You agree with that?A. I agree with that.
4 5	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market	3 4 5	Q. You agree with that?A. I agree with that.Q. Okay. Do you know anybody else
4 5 6	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the	3 4 5 6	Q. You agree with that?A. I agree with that.Q. Okay. Do you know anybody else in the world who agrees with that opinion
4 5 6 7	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market	3 4 5 6 7	Q. You agree with that?A. I agree with that.Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold?
4 5 6 7 8	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a	3 4 5 6 7 8	 Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so
4 5 6 7 8 9	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe.	3 4 5 6 7 8	 Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't
4 5 6 7 8 9	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align.	3 4 5 6 7 8 9	 Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that.
4 5 6 7 8 9 10	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name.	3 4 5 6 7 8 9 10	 Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't
4 5 6 7 8 9 10 11	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align.	3 4 5 6 7 8 9 10 11 12	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this
4 5 6 7 8 9 10 11 12 13	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that?	3 4 5 6 7 8 9 10 11 12 13	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate
4 5 6 7 8 9 10 11 12 13 14	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a	3 4 5 6 7 8 9 10 11 12 13 14	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this
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4 5 6 7 8 9 10 11 12 13 14 15	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or
4 5 6 7 8 9 10 11 12 13 14 15 16	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to
4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT®
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes. Q. Several? A. Yes. Q. Have you ever had to remove a	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT® risks so outweigh its benefits that it never
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes. Q. Several? A. Yes. Q. Have you ever had to remove a Desara?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT® risks so outweigh its benefits that it never should have been on the market?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes. Q. Several? A. Yes. Q. Have you ever had to remove a Desara? A. I removed a Desara TOT. I have	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT® risks so outweigh its benefits that it never should have been on the market? A. It says that exact statement?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No, but I see how many of each I remove, and it's the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe. Q. Have you ever had to remove a BARD I've already forgotten the name. A. Align. Q. No the one before that? A. Uretex? Q. Yes. Have you ever had to remove a BARD Uretex? A. Yes. Q. Several? A. Yes. Q. Have you ever had to remove a Desara?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You agree with that? A. I agree with that. Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold? A. I don't know a lot of people so I'm really I really shouldn't can't answer that. Q. Well, the answer is you don't know anyone that shares that opinion, true? A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are. Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT® risks so outweigh its benefits that it never should have been on the market?

1 statement. 2 A. I think there's papers that 3 state that there's degradation of the mesh 4 and there is a paper that says that the 5 complications are not what's really reported 6 in the literature. So some of the 7 complications that were seen are skewed in a 8 very specific way. 9 Q. Okay. Which paper is that? 10 A. I think the rame was Anger. 11 Q. And what's the paper that says 12 there's degradation? 13 A. That would be Clavé. 14 Q. Was that in vivo degradation 15 that was reported by Clavé? 16 A. Yes. 17 Q. So back to my original question 18 because that wasn't quite — I appreciate 19 that information, but that wasn't quite the 20 answer. 21 Is there any paper you can 22 point to that you believe reaches the 23 conclusion — I'll Change it a little bit — 24 that reaches the conclusion that the risks of 25 because they're not seeing these women with 6 all these complications. Feven I have not 7 reported all my complications. Not my 8 complications. Feven I have not 9 Page 43 1 TVT® outweigh the benefits so that it never 2 should have been sold? 3 A. I don't think that al to of 4 surgeons have the viewpoint that I have 5 because they're not seeing these women with 6 all these complications. Even I have not 7 reported all my complications. Not my 8 complications. Feven I have not 9 Page 45 1 Q. We're not into 2017 so it can't 18 paper. 19 Q. So the answer to my question is 19 Q. So the answer to my question is 20 quite to support that view just yet. 21 Q. So the answer to my question is 22 quite that there's anyone that's 23 quite that there's anyone that's 24 going to support that view just yet. 25 quite that there's anyone that's 26 don't think that there's anyone that's 27 quite the paper that the paper is that there's anyone that's 28 quite the paper that a serve that the paper that		Page 42		Page 44
2 A. I think there's papers that 3 state that there's degradation of the mesh 4 and there is a paper that says that the 5 complications are not what's really reported 6 in the literature. So some of the 7 complications that were seen are skewed in a 8 very specific way. 9 Q. Okay. Which paper is that? 10 A. I think her name was Anger. 11 Q. And what's the paper that says 12 there's degradation? 13 A. That would be Clavé. 14 Q. Was that in vivo degradation 15 that was reported by Clavé? 16 A. Yes. 17 Q. So back to my original question 18 because that wasn't quite — I appreciate 19 that information, but that wasn't quite the 20 answer. 21 Is there any paper you can 22 point to that you believe reaches the 23 conclusion – I'll change it a little bit — 24 that reaches the conclusion that the risks of 4 surgeons have the viewpoint that I have 5 because they're not seeing these women with 6 all these complications. Even I have not 7 reported all my complications. Not my 8 complications, the patients that present. 9 So until that paper is written, 9 C. So the answer to my question is 10 I don't think that a lot of 21 surgeons have the viewpoint that I have 22 should have been sold? 23 A. I don't think that a lot of 24 surgeons have the viewpoint that I have 25 because they're not seeing these women with 26 all these complications. Even I have not 27 reported all my complications. Not my 28 complications, the patients that present. 9 G. So the answer to my question is 11 going to support that view just yet. 12 Q. So the answer to my question is 13 you're not able to point to any study or any 14 literature or any paper that expresses the 15 opinion that you have that he risks of TVT® 16 outweigh the benefits so that it never should 17 have been sold? 18 A. No paper that I know of. 19 Q. Now, how many TVT® have you 19 Robert and the paper is that? 20 Poly and the paper is that? 21 I have been sold? 22 Cokay. Do you have any estimate 23 Go Roby and did you reference any papers 24 I have been sold? 25 A. I did. 26 Okay. Do	1	statement.	1	A. Several hundred.
state that there's degradation of the mesh and there is a paper that says that the complications are not what's really reported in the literature. So some of the complications that were seen are skewed in a very specific way. 9 Q. Okay. Which paper is that? 10 A. I think I am. 11 Q. And what's the paper that says 12 there's degradation? 12 there's degradation? 13 A. That would be Clavé. 14 Q. Was that in vivo degradation 15 that was reported by Clavé? 16 A. Yes. 17 Q. So back to my original question 18 because that wasn't quite I appreciate 19 that information, but that wasn't quite the answer. 20 answer. 21 Is there any paper you can 22 point to that you believe reaches the 23 conclusion I'll change it a little bit 24 that reaches the conclusion that the risks of 25 that reaches the conclusion that have been sold? 26 So until that paper is written, 27 Page 43 28 TVT® outweigh the benefits so that it never 29 should have been sold? 31 A. I don't think that at lot of 32 surgions have the viewpoint that I have 33 because they're not seeing these women with 34 all these complications, key altenthat paper is written, 35 Q. Okay. Is that referenced in 36 your report anywhere on TYT®? 36 A. I don't think so. 37 A. I don't think so. 38 Q. Okay. Is that referenced in 39 your report anywhere on TYT®? 39 You know which study I'm 40 (D. Wo're aware of a - it's a 41 TVT® and reported 41 Twas hesitating for a second because I think 41 there's a 2008 paper and there's one that 42 that reaches the conclusion that the risks of 42 that reaches the conclusion that the risks of 43 A. I don't think that a lot of 44 surgeons have the viewpoint that I have 45 because they're not seeing these women with 46 all these complications, Even I have not 47 reported all my complications. Not my 48 complications, the patients that present. 49 So until that paper is written, 40 Q. So the answer to my question is 50 unil that paper is written, 51 Q. So the answer to my question is 51 qoint to that you believe reaches the 52 qoint thi			2	
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as to how many you've removed in your career? 24 MK. MATTHEWS: Well, I	22	2015. 34 retropubic.		
	22 23	2015. 34 retropubic. Q. Okay. Do you have any estimate	23	be contrary to that opinion?

12 (Pages 42 to 45)

	Page 46		Page 48
1	didn't object to the form of the	1	the TVT®?
2	question.	2	A. There is.
3	THE WITNESS: There are so many	3	Q. Would you show me where that
4	papers on TVT®, it's not possible to	4	is?
5	reference all the papers.	5	A. Sure.
6	QUESTIONS BY MR. BALL:	6	It's on page 9. It starts on
7	Q. Okay. Why did you not	7	page 9.
8	reference the Nilsson 17-year study paper?	8	It says the force required to
9	A. I have a little problem with	9	implant the TVT® with the metal introducers
10	that paper. That paper started with 90	10	deforms the mesh and the mesh can also deform
11	patients, if I remember the one that's	11	after implantation. The design of the TVT®
12	correct, and by the time they followed those	12	trocar, size, arc, handle with the TVT® mesh
13	patients, half they only followed half,	13	is a design mismatch for the pelvis
14	which was 45 patients. That's not an	14	Q. I understand.
15	adequate sample of a longitudinal study.	15	I didn't get that one. Now
16	Q. Which paper referenced in your	16	with your explanation earlier, I understand
17	report do you believe does not support your	17	what you're saying there.
18	conclusion that the risks of TVT® outweigh	18	A. Okay.
19	the benefits?	19	Q. So I appreciate that.
20	A. That would be the Thomas study,	20	A. Okay.
21	trial of midurethral sling.	21	Q. Do you believe that most
22	Q. What does it say?	22	doctors that well, strike that.
23	A. They compared retropubic sling	23	The TVT® has been used millions
24	to TOT to see if they both kind of were	24	of times in surgery over the years, true?
21	to 101 to see if they both kind of were	24	of times in surgery over the years, true:
	Page 47		Page 49
1	equal. Partially because there's so many	1	A. I don't I'm sure. I don't
2	retropubic injuries and traumas from passage	2	know the exact number. I'll take your word
3	of those trocars, which, in my opinion, is	3	for it.
4	related to the technique, and that report	4	Q. You wouldn't disagree with
5	shows that at one year it seems like both	5	that?
6	slings are pretty equal. That's a good	6	A. No.
7	paper.	7	Q. And the great majority of those
8	The problem with the paper is	8	times that it has been used, it's been
9	it's only one year. It really didn't look at	9	successful?
10	all the issues that occur years later. Most	10	A. I don't know what the overall
11	of these women that I'm seeing in my practice	11	success rate in those millions is.
12	aren't showing up a year after a sling.	12	Q. The great majority of the time
13	They're showing up five, six, seven, eight,	13	that the TVT® has been used in surgery, it's
14	nine years later, and some of these problems	14	been used with the instrumentation and the
15	have persisted for years.	15	technique recommended by Ethicon, true?
16	Q. The Thomas paper did not	16	A. I don't know anyone else that's
17	address the risk versus benefits of just the	17	using the technique that I'm using.
18	TVT®, did it?	18	Q. Okay.
19	It was a comparison between the	19	A. Except my partner. I am sorry.
20	TVT® and the TVT-O?	20	Q. You don't know anyone else
21	A. TVT®, TVT-O and Monarc.	21	that's using any different technique than
22	Q. Is there anywhere in Exhibit 2	22	what's recommended by the
23	where you expressed criticism of the	23	A. No. As I mentioned earlier,
24	technique or instrumentation with respect to	24	it's not something that I discuss with folks

Page 50 Page 52 1 a lot. 1 lead to my next question. 2 Do you have an opinion as to 2 Do you have an opinion -- see Q. 3 3 what the success rate is with the -- if done if this was what you were getting ready to 4 by a surgeon using the technique and 4 5 instrumentation recommended by the 5 Do you have an opinion as to 6 6 manufacturer, do you have an opinion as to the percentage of complications? Is that 7 7 what the success rate is with the TVT®? what you're going to be talking about, or no? 8 8 A. I do. A. No. 9 Q. Okay. What is that opinion? 9 What do you mean when you said Q. 10 10 The original success rate by for the percentage of the leaking part? Ulmsten was basically 85 percent cure. It 11 11 A. That's what 85 percent success was sadly 11 percent improvement. But it's 12 12 refers to, which is the testing they did 85 percent cure, about 7 percent improvement, 13 13 afterwards on pad testing and cough stress about 7, 8 percent didn't have an 14 14 test. That's how they measured the success. 15 improvement. That was original data by 15 Q. So if it stopped completely, 16 Ulmsten. 16 that was a cure? 17 The data by the Thomas trial 17 A. Yes. 18 was a little bit less. 18 And if it improved it, that was 19 So what is your opinion with 19 an improvement? regard to the success rate of the TVT®, if 20 20 Correct. A. 21 you have an opinion? 21 Q. All right. I'm with you. 22 Now, new question, do you have Based upon review of the 22 23 literature, your own knowledge, do you have 23 an opinion as to the complication rate -- and 24 an opinion as to what the success rate is 24 by that I don't mean temporary, I mean Page 51 Page 53 1 long-term complication rate -- with TVT®? with the TVT®? 1 2 A. So my --2 A. I don't think that anyone can 3 3 MR. MATTHEWS: Hold on. Object answer that question. 4 Okay. So you don't have an 4 to the form because I don't know what 5 5 you mean by the definition of "success opinion? 6 6 rate." A. I have an opinion. 7 **OUESTIONS BY MR. BALL:** 7 Q. Okay. Your opinion, I can't 8 Q. Okay. Go ahead. 8 answer it? 9 A. I read the papers, and I see 9 Well, I can't give you a 10 numbers from 40 to 90. So my opinion is 10 percentage. I guess what I was thinking, to 11 based on the success rate of those individual 11 be very transparent, give you a number like I 12 groups of patients that are reported. I have 12 gave you for the treatment of incontinence. a very biased view because I see patients 13 I can't give you a number because I'm sure 13 14 that have failure with leaking. And if someone knows the denominator of how many 14 15 you're only measuring the success rate, not 15 slings went in, but -- or maybe the 16 leaking, it's about what those papers report. 16 numerator, no one knows the other number of 17 17 Q. Okay. So let me make sure. So how many people are having problems. I know 18 your opinion would be that the success rate 18 what problems I see, and I've not reported 19 with TVT® is approximately 85 percent cure 19 all these for any manufacturer. 20 and about 7 percent improvement, and about 7 20 I know other doctors are taking 21 or 8 percent no improvement? 21 care of problems. But there hasn't been a 22 A. That's right. For the 22 national registry in the United States that 23 treatment of the leaking part. 23 looks at how many went in and what the 24 Q. Okay. I think that's going to 24 problems are.

	Page 54		Page 56
1	Q. Okay.	1	Like if you take all of your
2	A. And until that happens, it's	2	SUI treatments in the last few years, what
3	hard to estimate.	3	percentage has been non-mesh?
4	Q. Do you have do you tell your	4	A. It's going up. It's about
5	patients what the likelihood of complications	5	15 percent now.
6	is with in terms of percentages with an	6	Q. 15?
7	SUI procedure?	7	A. 15.
8	A. The way I do it and what I do,	8	Q. What methods do you use?
9	yes, I do.	9	A. Either autologous fascia or
10	Q. What do you say?	10	cadaveric fascia.
11	A. 2 percent retention rate.	11	Q. Autologous means what?
12	Q. 2 percent will have a retention	12	A. I remove a little bit of fascia
13	problem?	13	from the patient's own body.
14	A. 2 percent will have a retention	14	Q. Where do you remove it from?
15	problem requiring an adjustment of the sling,	15	A. Either the abdomen or the leg.
16	not a removal.	16	It depends whether they have had hip
17	Q. Okay. Can you tell me anything	17	replacement or if they've had multiple
18	else about complication rates?	18	surgeries.
19	A. Bleeding.	19	Q. And what do you do, fashion a
20	Q. Can you give percentages on any	20	sling out of that?
21	of these?	21	A. Yes. It's a basically a small
22	A. It's very rare. I've not	22	little strip.
23	transfused a patient from an SUI procedure in	23	Q. And then cadaveric is the same?
24	years.	24	A. Yes.
	Page 55		Page 57
1	I talk about bladder injury	1	Q. It's a piece of tissue from
2	because I get patients that have previous	2	another body?
3	slings or previous other procedures.	3	A. Yes.
4	Q. Now, I'm going to get into all	4	Q. That you fashion into a sling?
5	of the possible complications here in a	5	A. Yes.
6	minute.	6	Q. How is it or why is it that
7	What I was asking is in terms	7	you use one of those two?
8	of in your practice over the last 10 or	8	Do you use either one of those
9	15 years, have you given patients any	9	more than the other?
10	percentage? And you mentioned that you tell	10	A. I give those options to the
11	them there's a 2 percent urinary retention.	11	patient. Every patient with SUI now has a
12	A. Incomplete bladder emptying	12	conversation regarding mesh and complications
13	retention.	13	and what they've seen on the news and heard
14	Q. Any other percentages that you	14	on the radio.
	give them?	15	Q. Do you have to use sutures in
15		16	connection with those autologous or cadaveric
16	A. No.	1	
16 17	Q. In terms of complications?	17	slings?
16 17 18	Q. In terms of complications?A. That's the only one, because	17 18	slings? A. The approach I use is exactly
16 17 18 19	Q. In terms of complications?A. That's the only one, becauseall the other things with the technique I	17 18 19	slings? A. The approach I use is exactly the same whether I'm using synthetic,
16 17 18 19 20	Q. In terms of complications? A. That's the only one, because all the other things with the technique I employ are exceedingly rare.	17 18 19 20	slings? A. The approach I use is exactly the same whether I'm using synthetic, autologous or cadaver.
16 17 18 19 20 21	 Q. In terms of complications? A. That's the only one, because all the other things with the technique I employ are exceedingly rare. Q. Do you ever use non-mesh for 	17 18 19 20 21	slings? A. The approach I use is exactly the same whether I'm using synthetic, autologous or cadaver. Q. Do you have to use sutures?
16 17 18 19 20 21	 Q. In terms of complications? A. That's the only one, because all the other things with the technique I employ are exceedingly rare. Q. Do you ever use non-mesh for SUI? 	17 18 19 20 21 22	slings? A. The approach I use is exactly the same whether I'm using synthetic, autologous or cadaver. Q. Do you have to use sutures? A. Yes.
16 17 18 19 20 21	 Q. In terms of complications? A. That's the only one, because all the other things with the technique I employ are exceedingly rare. Q. Do you ever use non-mesh for 	17 18 19 20 21	slings? A. The approach I use is exactly the same whether I'm using synthetic, autologous or cadaver. Q. Do you have to use sutures?

15 (Pages 54 to 57)

	Page 58		Page 60
1	A. No.	1	option.
2	Q. What are they?	2	Q. How many of those do you think
3	A. Polyglyconate suture. It's	3	you've done in the last ten years?
4	Vicryl Polysorb.	4	A. Last ten years?
5	Q. They're absorbable?	5	30, 40.
6	A. Yes.	6	Q. And that was when you already
7	Q. This 15 percent, is this just	7	had to have an abdominal incision anyway?
8	patient's choice?	8	A. Yes.
9	A. Yes.	9	Q. Okay. Is acute or chronic pain
10	Q. Or do you recommend one versus	10	a risk of a non-mesh SUI surgery?
11	the other?	11	A. Acute pain can be.
12	A. I give them the options.	12	Q. Not chronic pain?
13	Q. Okay. And so that 15 percent	13	A. Huh-uh.
14	now these days are choosing the cadaveric?	14	Q. Is acute or chronic pain with
15		15	=
16		16	intercourse a potential risk of non-mesh
17	2	17	surgery? A. No.
	Am I saying that right,		
18 19	autologous? A. Yes.	18	Q. So having pain with intercourse
		19	after an SUI surgery, non-mesh, is not a risk
20	Q. When did you start that?	20	at all?
21	A. I've always done autologous	21	A. It's virtually unheard of.
22	slings.	22	Q. Is vaginal scarring a risk with
23	Q. No. I meant when did you start	23	non-mesh SUI surgery?
24	giving them, saying, "Here are the three	24	A. Typically, no.
	Page 59		Page 61
1	choices, what do you want to do?"	1	Q. Is infection a risk with
2	When did you start that?	2	non-mesh SUI surgery?
3	A. The last few years. I can't	3	A. You can get a hematoma and
4	remember exactly when.	4	infection, yes.
5	Q. Okay. Other than any other	5	Q. Is urinary frequency, urgency,
6	type of you don't use the Burch procedure	6	dysuria, retention or obstruction or
7	anymore?	7	incontinence, are those risks of non-mesh SUI
8	A. If they ask, but typically I'm	8	surgery?
9	doing a lot of vaginal surgery and the Burch	9	A. Yes.
10	procedure would necessitate an incision. If	10	Q. Are UTIs as a result of
11	I'm doing	11	retention a risk of non-mesh SUI surgery?
12	Q. An abdominal incision?	12	A. Yes.
13	A. Yes. If I'm doing an abdominal	13	Q. Is organ or nerve damage a risk
14	approach, when I'm right there.	14	of non-mesh SUI surgery?
15	The reason I switched to a less	15	A. Can be, yes.
16	invasive sling was not to make the abdominal	16	Q. Okay. Is bleeding a risk with
17	incisions and et cetera.	17	non-mesh SUI surgery?
18	Q. Right.	18	A. Absolutely.
19	So you don't do very many	19	Q. Wound complications?
20	Burches anymore?	20	A. Sometimes.
21	A. I never really did.	21	Q. Inflammation?
22	Q. And how about MMK?	22	A. Short-term inflammation.
23	A. It's a variation of a Burch. I	23	Q. Fistula formation?
24	always preferred the Burch, but the MMK is an	24	A. No.
	armays preferred the Duren, but the Ivilvin is all	4	11. 110.

16 (Pages 58 to 61)

	Page 62		Page 64
1	Q. How about are neuromuscular	1	subject to potential foreign body responses?
2	problems in the pelvic floor muscles, the	2	A. In the short term.
3	lower extremities or the abdominal area, are	3	Q. That type of suture, can it
4	those risks of non-mesh SUI surgery?	4	have erosion or exposure?
5	A. I'm not sure I understand that	5	A. Sometimes.
6	last question.	6	Q. In a non-mesh SUI surgery?
7	Q. Okay. You don't know what a	7	A. Yes.
8	neuromuscular	8	Q. And is contraction of tissues a
9	A. I do, but they were all kind of	9	risk in a non-mesh SUI surgery?
10	lumped together.	10	A. No.
11	Q. Okay. Can you have let me	11	Q. Okay. Now, is there any risk
12	unlump then.	12	related to the mesh that is present with the
13	Can you have neuromuscular	13	TVT® mesh that is not present with the Desara
14	problems in the pelvic floor muscles related	14	mesh?
15	to non-mesh SUI surgery?	15	A. Yes.
16	A. You can.	16	Q. Okay. What is that?
17	Q. How about neuromuscular	17	A. The Desara does not fray. It's
18	problems in the lower extremities?	18	a very stable weave.
19	A. Not related to the procedure,	19	Q. Okay. By fray, you mean what?
20	no.	20	On the edges?
21	Q. What about in the abdominal	21	A. On the edges. It doesn't
22	area?	22	deform when you pull on it.
23	A. If you're harvesting the tissue	23	Q. Okay. So have you ever seen
24	from there, yes.	24	evidence of fraying in any TVT® that caused
	, ,		
	Page 63		Page 65
1	Q. Okay. Is recurrent surgery a	1	any clinical problem in your view?
2	risk of non-mesh SUI surgery?	2	A. Yes.
		4	Α. 165.
3	A. Yes.	3	Q. Okay. Tell me about that.
3	A. Yes.	3	Q. Okay. Tell me about that.
3 4	A. Yes.Q. And is a foreign body response	3 4	Q. Okay. Tell me about that.A. So when I first started
3 4 5	A. Yes.Q. And is a foreign body response from sutures a risk of a non-mesh SUI	3 4 5	Q. Okay. Tell me about that.A. So when I first startedfirst of all, when it first became blue is
3 4 5 6	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery?	3 4 5 6	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would
3 4 5 6 7	 A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes 	3 4 5 6 7	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would
3 4 5 6 7 8	 A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable 	3 4 5 6 7 8	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions
3 4 5 6 7 8 9 10	 A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in 	3 4 5 6 7 8 9 10 11	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were
3 4 5 6 7 8 9 10 11	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery?	3 4 5 6 7 8 9	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing?
3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do.	3 4 5 6 7 8 9 10 11	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there.
3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable?	3 4 5 6 7 8 9 10 11 12	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay.
3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's	3 4 5 6 7 8 9 10 11 12 13	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that
3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do.	3 4 5 6 7 8 9 10 11 12 13 14	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is	3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is different. Most will use a non-monofilament	3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is different. Most will use a non-monofilament suture because if you touch it with the forceps or you tie it, it fractures and it	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off of the implant. So when you lose part of the
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is different. Most will use a non-monofilament suture because if you touch it with the forceps or you tie it, it fractures and it breaks and it fails. So most of us that do	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off of the implant. So when you lose part of the weave, the mesh elongates and ropes and cords
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is different. Most will use a non-monofilament suture because if you touch it with the forceps or you tie it, it fractures and it breaks and it fails. So most of us that do different kinds of surgeries will use a	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off of the implant. So when you lose part of the weave, the mesh elongates and ropes and cords and twists and rolls, and as soon as it does that, it goes from being whatever its gram per meter squared weight is, it's immediately
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery? A. If you use a polypropylene suture. Q. Okay. Are sometimes polypropylene is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery? A. Some do. Q. It's acceptable? A. I don't know if it's acceptable; some do. The tensile strength is different. Most will use a non-monofilament suture because if you touch it with the forceps or you tie it, it fractures and it breaks and it fails. So most of us that do different kinds of surgeries will use a non-monofilament polypropylene suture.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay. Tell me about that. A. So when I first started first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall. Q. And what clinical issues were those causing? A. I'm getting there. Q. Okay. A. I'm getting to that. So that was the first observation. So that came off of the implant. So when you lose part of the weave, the mesh elongates and ropes and cords and twists and rolls, and as soon as it does that, it goes from being whatever its gram
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	Page 66		Page 68
1	very, very important is that the pores	1	Q. Which is lighter weight, the
2	coalesce. So whatever the pores when it's	2	Desara or the TVT®?
3	sitting on the table before it's implanted,	3	A. They're the same weight.
4	once it's implanted with any type of force on	4	Q. Okay. Which has larger pores,
5	it, the pores the effective pore size	5	the Desara or the what do you call it, the
6	becomes very small.	6	opposite of in vivo?
7	Q. Have you ever measured the	7	When it comes out of the box,
8	effective pore size on a TVT®?	8	which has larger pores, Desara or TVT®?
9	A. Personally, no.	9	A. Desara.
10	Q. Okay. Are you aware of any	10	Q. Do you know the dimensions of
11	study that has done that?	11	the Desara sling?
12	A. I've seen documentation inside	12	A. You mean the pore size?
13	the Ethicon documents that tells me what the	13	Q. Yeah.
14	pore size it.	14	A. Yeah, it's approximately
15	Q. In vivo?	15	1,200 microns.
16	A. Not in vivo.	16	Q. What is the size of the TVT®
17	Q. Okay. So do you have an	17	pores?
18	opinion as to what the effective pore size in	18	A. About a thousand microns.
19	vivo is in a TVT®?	19	Q. What is the size what was
20	A. I do.	20	the size of the Uretex?
21		21	A. 1,160.
22	Q. Okay. What is it?A. It's less than before it got	22	,
23	implanted.	23	Q. Do you have an opinion as to what the pore size in the body is of the
24	÷	24	Desara or the Uretex?
24	Q. Do you have anything more	24	Desara of the Ofelex?
	Page 67		Page 69
1	precise than that?	1	A. I do.
			A. I uo.
2	A. Sometimes there is no pores.	2	Q. What is it?
3	A. Sometimes there is no pores. It completely coalesces very easily. The	2 3	
	•		Q. What is it?
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3 4	It completely coalesces very easily. The stretchability of the mesh is desirable, but	3 4	Q. What is it? A. It's greater than 1,160, greater than 1,200.
3 4 5	It completely coalesces very easily. The stretchability of the mesh is desirable, but the problem with it is that it deforms so much that it there's virtually no pore. It's a tiny little slit.	3 4 5	Q. What is it?A. It's greater than 1,160,greater than 1,200.Q. They get bigger?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	It completely coalesces very easily. The stretchability of the mesh is desirable, but the problem with it is that it deforms so much that it there's virtually no pore. It's a tiny little slit. Q. By the Amid classification is the mesh in TVT® a large pore mesh? A. By the Amid classification, yes. Q. In your view is it generally recognized that the TVT® is a large pore mesh? A. Oh, by Ethicon's documentation is considered microporous. Q. In the medical community, is it generally is the TVT® mesh generally regarded as a macroporous mesh? A. Before it's implanted, yes. Q. In the medical community, is the TVT® mesh generally regarded as lightweight?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. What is it? A. It's greater than 1,160, greater than 1,200. Q. They get bigger? A. I make them bigger. Q. Okay. How do you do that? A. I am sorry, I was a little remiss. I didn't mention that when I place the sling in the midurethra, I sew it in a configuration I attach it with absorbable sutures in a configuration that opens the pores up more. Q. Is that recommended in the IFUs for either Uretex or Desara? A. No. Q. So if you didn't do that technique, do you have an opinion as to what the effective pore size would be for the Desara or the Uretex? A. I do not. Q. It would be something less than they're designed?
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2 A. And when I tried to do that 3 with TVT®, I couldn't because of the edges 4 fraying. 4 Q. Why? 5 Q. Okay. 6 A. When I tried those two. But I 7 always thought that the pores on all the 8 slings that came after the Ethicon Mersilence 9 were small because I was spoiled. I was used 10 to seeing large pores where I could open the 11 tissue up and if you held and just looked for 12 a second, you could actually see the turgor 13 pressure of the tissue coming through the 14 pores before the operation was done. So 15 having that visual confirmation and then not 16 having it with polypropylen made me think. 17 Q. Did you think the pores, the 18 preimplantation pore size, was larger in 19 Mersilene? 20 A. It's definitely larger. 21 Q. What is it? 22 A. 23 – 2.3 millimeters. 23 Q. 2,300? 24 A. Yes. 25 Page 71 1 Q. Microns? 26 A. Yes. 27 A. Yes. 3 Q. Okay. I can't remember what 4 you said. The Desarra and the Uretex, were 4 those lightweight meshes? 4 C. Why? 4 A. I've read in the Ethicon Page 71 1 Q. Microns? 5 A. Yes. 2 A. Yes. 3 Q. Okay. I can't remember what 4 you said. The Desarra and the Uretex, were 5 those lightweight meshes? 4 A. So the Uretex was 81 grams per 5 meter squared. So that was lighter than all 8 the others. So if you take a look at all the 6 current slings that are on the market, 10 they're all at about 100. Boston Scientific, 11 Desara, Align. 12 Q. And TVT®; 13 A. Yes, and they're all too heavy. 14 Q. Okay. 15 A. They're all too heavy. 15 A. They're all too heavy. 16 Q. Everything that's on the market 17 today is too heavy? 18 A. Everything that's on the market 19 is a problem. 20 Q. Is the pore size for the – not 21 counting you're spreading it out when you 22 implant it, is the pore size acceptable on 24 Q. Have you written – have you 25 Unexpression of the deges 26 A. So the Uretex was 81 grams per 27 A. Not slings, no. 28 Q. Okay. Talking about the 29 Shouther fraying and the 29 Shouth that the TVT® mesh falling apart, pieces coming 29 Okay. Talking about the 29 Shouth that the was energeni
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17 Q. Did you think the pores, the preimplantation pore size, was larger in 19 Mersilene? 20 A. It's definitely larger. 21 Q. What is it? 22 A. 23 2.3 millimeters. 23 Q. 2,300? 24 A. Yes. Page 71 1 Q. Microns? 24 A. Yes. Page 71 1 Q. Microns? 25 A. Yes. Page 71 1 Q. Microns? 26 A. Yes. Page 71 1 Q. Microns? 27 A. Yes. Page 71 1 Q. Microns? 28 A. Yes. Page 71 1 Q. Microns? 29 A. Yes. Page 71 1 Q. Microns? 20 Q. Have you read any study that the TVT® mesh falling apart, pieces coming off it, have been a clinical problem for anyone? Page 73 A. I've read in the Ethicon Page 73 A. Yes occurrents that people complained that it was fraying. Q. Have you read any published scientific literature where fraying and the tothers. So if you take a look at all the current slings that are on the market, they're all at about 100. Boston Scientific, 10 Desara, Align. Desara, Align. Q. And TVT®? A. Yes, and they're all too heavy. 4 Q. Okay. 4 A. They're all too heavy. 4 Q. Okay. 4 A. They're all too heavy. 5 A. They're all too heavy. 6 Q. Everything that's on the market today is too heavy? 7 A. Not slings, no. 8 Q. Doy ou generally in reaching medical opinions rely upon internal e-mails and internal documents? 10 Q. Have you written have you written have you
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14 Q. Okay. 15 A. They're all too heavy. 16 Q. Everything that's on the market 17 today is too heavy? 18 A. Everything that's on the market 19 is a problem. 20 Q. Is the pore size for the not 21 counting you're spreading it out when you 22 implant it, is the pore size acceptable on 14 internal documents? A. Not for slings. Q. About their slings? A. Not slings, no. Q. Do you generally in reaching medical opinions rely upon internal e-mails and internal documents? A. No. 22 Q. Have you written have you
A. They're all too heavy. Q. Everything that's on the market today is too heavy? A. Not for slings. Q. About their slings? A. Not slings, no. A. Not slings, no. A. Not slings, no. Q. Do you generally in reaching medical opinions rely upon internal e-mails Q. Is the pore size for the not counting you're spreading it out when you implant it, is the pore size acceptable on 20 Q. Have you written have you
16 Q. Everything that's on the market 17 today is too heavy? 18 A. Everything that's on the market 19 is a problem. 19 Q. About their slings? 19 medical opinions rely upon internal e-mails 20 Q. Is the pore size for the not 21 counting you're spreading it out when you 22 implant it, is the pore size acceptable on 26 Q. About their slings? A. Not slings, no. 27 medical opinions rely upon internal e-mails 28 and internal documents? 29 A. No. 20 Rave you written have you
today is too heavy? 17 A. Not slings, no. 18 A. Everything that's on the market 19 is a problem. 19 Q. Do you generally in reaching 19 medical opinions rely upon internal e-mails 20 Q. Is the pore size for the not 20 and internal documents? 21 counting you're spreading it out when you 22 implant it, is the pore size acceptable on 23 Q. Have you written have you
A. Everything that's on the market is a problem. Q. Do you generally in reaching medical opinions rely upon internal e-mails and internal documents? Q. Is the pore size for the not counting you're spreading it out when you implant it, is the pore size acceptable on counting you written have you implant it, is the pore size acceptable on counting you written have you
19 is a problem. 20 Q. Is the pore size for the not 21 counting you're spreading it out when you 22 implant it, is the pore size acceptable on 29 medical opinions rely upon internal e-mails 20 and internal documents? 21 A. No. 22 Q. Have you written have you
20 Q. Is the pore size for the not 20 and internal documents? 21 counting you're spreading it out when you 21 A. No. 22 implant it, is the pore size acceptable on 22 Q. Have you written have you
21 counting you're spreading it out when you 21 A. No. 22 implant it, is the pore size acceptable on 22 Q. Have you written have you
22 implant it, is the pore size acceptable on 22 Q. Have you written have you
23 the Desara as far as you're concerned? 23 published in the medical field?
the Desara as far as you're concerned? 23 published in the medical field? 24 A. Yes. 24 A. Yes.
A. 105.

	Page 74		Page 76
1	Q. Have you ever cited an internal	1	what you've cited in your report?
2	document when writing in a peer-reviewed	2	Do you know that?
3	journal?	3	A. I don't know that.
4	A. No.	4	Q. Were you given any testimony of
5	Q. Do you think citations of	5	Ethicon witnesses to review?
6	internal company documents in a peer-reviewed	6	A. Yes.
7	journal would be acceptable?	7	Q. Okay. Was that also sent to
8	A. No.	8	you by the lawyer?
9	Q. Okay. Have you ever been a	9	A. Yes.
10	reviewer?	10	Q. Is what was sent to you also on
11	A. Yes.	11	the thumb drive and the CD?
12	Q. Okay. And if you were given a	12	A. I've not seen the thumb drive.
13	paper that based opinions upon internal	13	Q. Okay.
14	company documents, would you reject that	14	A. I've not opened it. The CD, I
15	paper as a reviewer?	15	believe, are my reports only.
16	A. It's a good question. I don't	16	Q. Does your report refer to all
17	know what I would do. I would find it very	17	of the deposition testimony that you've been
18	different because you don't normally have	18	given?
19	that.	19	A. No.
20	Q. Do you believe that you gave a	20	Q. Okay. How do I know which
21	fair representation of the overall Ethicon	21	testimony you've been given?
22	documents that you cited in your paper?	22	A. I guess it's on the thumb
23	A. Yes.	23	drive.
24	Q. How many Ethicon documents did	24	Q. Okay. And so if there was
	Page 75		Page 77
1	you review?	1	did you read all of the Ethicon testimony
2	A. I reviewed everything they sent		
		2	that's been given?
3	me. I can't even tell you.	3	A. Yes.
3 4	me. I can't even tell you. Q. That's a key part.	3 4	_
4 5	me. I can't even tell you. Q. That's a key part. Did you review anything that	3 4 5	A. Yes.Q. It was on the thumb drive?A. Yes.
4 5 6	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon	3 4 5 6	A. Yes.Q. It was on the thumb drive?A. Yes.Q. Every word of it?
4 5	me. I can't even tell you. Q. That's a key part. Did you review anything that	3 4 5	A. Yes.Q. It was on the thumb drive?A. Yes.
4 5 6	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to	3 4 5 6 7 8	 A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir.
4 5 6 7 8 9	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it.	3 4 5 6 7 8 9	 A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you
4 5 6 7 8 9	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent	3 4 5 6 7 8 9	 A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about
4 5 6 7 8 9 10	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you?	3 4 5 6 7 8 9 10	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents?
4 5 6 7 8 9 10 11	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents?	3 4 5 6 7 8 9 10 11	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know.
4 5 6 7 8 9 10 11 12 13	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes.	3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a
4 5 6 7 8 9 10 11 12 13 14	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents?	3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up.
4 5 6 7 8 9 10 11 12 13 14 15	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages.	3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced
4 5 6 7 8 9 10 11 12 13 14 15 16	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on	3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to
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4 5 6 7 8 9 10 11 12 13 14 15 16	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on	3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to
4 5 6 7 8 9 10 11 12 13 14 15 16 17	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true? A. True.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon documents they sent you on the CD or the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon documents they sent you on the CD or the thumb drive?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true? A. True.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon documents they sent you on the CD or the thumb drive? A. I believe that's what	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true? A. True. MR. BALL: I like to take a
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	me. I can't even tell you. Q. That's a key part. Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer? A. No. I wouldn't have access to it. Q. Do you know how many they sent you? A. Documents? Q. Yes. A. Thousands and thousands of pages. Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon documents they sent you on the CD or the thumb drive? A. I believe that's what Mr. Matthews said.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. It was on the thumb drive? A. Yes. Q. Every word of it? A. To the best of my recollection, yes, sir. Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents? A. I don't know. Q. Okay. In order to do a strike that. Back up. To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true? A. True. MR. BALL: I like to take a break every hour.

	Page 78		Page 80
1	MR. BALL: No, I was done with	1	A. It did, but it was
2	that question.	2	multi-filament and that was the problem with
3	MR. MATTHEWS: Yeah, that's	3	it, and I wanted to do the best for my
4	fine.	4	patients, and knowing that, I switched.
5	(Off the record at 10:04 a.m.)	5	Q. So the standard became the
6	QUESTIONS BY MR. BALL:	6	acceptable standard was to use a lightweight,
7	Q. Doctor, your reports that have	7	monofilament, macroporous mesh for slings,
8	been submitted in this case, Exhibits 2 and	8	correct?
9	3, you would not submit those reports to a	9	A. Macroporous, monofilament. The
10	peer-reviewed journal for publication, true?	10	weight issue really didn't become important
11	A. They're not prepared for	11	for some time after that.
12	publication, no.	12	Q. Would you classify all of the
13	Q. And you would not use the same	13	Uretex and the TVT® and the Desara all as
14	technique and approach in preparing those	14	lightweight or heavyweight?
15	cases that you would if you were preparing a	15	A. They're all heavyweight.
16	scientific paper to be presented to	16	Q. Are they recognized in the
17	colleagues, true?	17	medical community to be heavyweight or
18	A. Yes. This is completely	18	lightweight?
19	different.	19	A. Heavyweight.
20	Q. Okay. Now, the fraying that	20	Q. Okay. Now, as we've said
21	you mentioned, did the Uretex have any of	21	earlier, obviously, at least hundreds, and
22	that propensity?	22	probably thousands, of surgeons have used
23	A. No, it had a weave	23	TVT® for SUI, true?
24	characteristic that I look for. So after	24	A. Yes.
	Page 79		Page 81
1	TVT® came out and I remember it was Will	1	Q. Okay. Are you critical of all
2	Irby that came and talked to me about it I	2	of those surgeons for using a product that
3	didn't find another product that I thought	3	should never have been on the market?
4	met my characteristics, qualifications the	4	A. I don't think they knew all of
5	characteristics of the Mersilene, until I saw	5	the things I knew or have my experience so I
6	Uretex, and the weave was in such a way that	6	can't be critical of them.
7	it did not fray.	7	Q. And by your experience, that
8	Q. Now, was the Uretex heavier or	8	means the one or two times you tried it?
9	lighter excuse me, the Mersilene, was that	9	A. No. No. No.
10	heavier or lighter?	10	My experience with being a
11	A. Much lighter. 33 grams per	11	surgeon of last resort that sees patients
12	meter squared.	12	that have problems.
13	Q. And why was it that the	13	For example, even in this
14	Mersilene what about it caused it to	14	community, Dr. Klutke was a preceptor for
тт	Tribibilities William de out it caused it to		, , , , , , , , , , , , , , , , , , ,
15	deteriorate early as you said earlier?	15	TVT®, and he would do surgery on patients,
		15 16	
15	deteriorate early as you said earlier?		TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly
15 16	deteriorate early as you said earlier? A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to	16 17 18	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor
15 16 17	deteriorate early as you said earlier? A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications and the	16 17 18 19	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly
15 16 17 18 19 20	deteriorate early as you said earlier? A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications and the Amid classification really was very important	16 17 18 19 20	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor of urology. He was one of the earlier adapters of the TVT®. He went to France and
15 16 17 18 19 20 21	deteriorate early as you said earlier? A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications and the Amid classification really was very important after the Gore-Tex because you needed	16 17 18 19 20 21	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor of urology. He was one of the earlier adapters of the TVT®. He went to France and all of those things. And I am not sure he
15 16 17 18 19 20 21	A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications and the Amid classification really was very important after the Gore-Tex because you needed 75 microns or larger to have macrophages	16 17 18 19 20 21	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor of urology. He was one of the earlier adapters of the TVT®. He went to France and all of those things. And I am not sure he knew how to deal with the complications or
15 16 17 18 19 20 21	deteriorate early as you said earlier? A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications and the Amid classification really was very important after the Gore-Tex because you needed	16 17 18 19 20 21	TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor of urology. He was one of the earlier adapters of the TVT®. He went to France and all of those things. And I am not sure he

	Page 82		Page 84
1	pattern of problems. The more I did that,	1	were alternatives available for different
2	the more patients found out and more docs	2	products to be developed, I may have put in a
3	found out I could help these problems and	3	bunch of slings and I may have, you know,
4	pretty soon I'm in the situation I'm in.	4	done it for not knowing what the
5	Q. Have any of the complications	5	consequences were.
6	that you've seen with the TVT® been related	6	Q. Did Mersilene have a foreign
7	to improper surgical technique?	7	body reaction?
8	A. They follow the technique	8	A. It did.
9	that's described. When I read the op notes,	9	Q. What was it made out of?
10	it reads like the way Ethicon set up the IFU.	10	A. Polyethylene terephthalate.
11	Q. Well, can a surgeon attempt to	11	Q. Was the foreign body reaction
12	follow what is set forth in the Ethicon IFU	12	any different with Mersilene than with
13	and make a mistake and not and then that	13	polypropylene?
14	leads to a complication?	14	A. I'm sure it's different.
15	A. They can change a technique	15	Q. Worse? Better?
16	like I've changed it, but can that be a	16	A. I don't know. I haven't seen
17	mistake in the hands of others? I assume so.	17	any data on that.
18	Q. So is it fair to say that your	18	Q. You mentioned foreign body
19	opinion that the TVT® should never have been	19	reaction.
20	sold based upon you using it one or two times	20	The other thing was, what,
21	and the fact that it was based primarily	21	deterioration of polypropylene, is that what
22	upon using it one or two times and what you	22	you said?
23	see from the people with complications?	23	A. Yes.
24	A. Would you repeat that?	24	Q. Did Mersilene deteriorate?
	, 1		
	Page 83		
	rage 03		Page 85
1	Q. Yeah.	1	Page 85 A. Not like polypropylene.
1 2		1 2	_
	Q. Yeah.		A. Not like polypropylene.
2	Q. Yeah. Is your opinion that the TVT®	2	A. Not like polypropylene.Q. Okay. So the polypropylene
2 3	Q. Yeah. Is your opinion that the TVT® never should have been on the market based	2 3	A. Not like polypropylene.Q. Okay. So the polypropyleneslings that you've used, aside from the one
2 3 4	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and	2 3 4	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the
2 3 4 5	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people	2 3 4 5	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara?
2 3 4 5 6	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery?	2 3 4 5 6	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes.
2 3 4 5 6 7	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read	2 3 4 5 6 7	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic
2 3 4 5 6 7 8	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date.	2 3 4 5 6 7 8	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction?
2 3 4 5 6 7 8 9	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to	2 3 4 5 6 7 8	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes.
2 3 4 5 6 7 8 9	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two	2 3 4 5 6 7 8 9	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to
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2 3 4 5 6 7 8 9 10 11 12	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am.
2 3 4 5 6 7 8 9 10 11 12	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am. Q. Have for 13 years?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market? A. So I'm having a little difficulty even in my own practice anymore using polypropylene knowing that there's a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am. Q. Have for 13 years? A. Yes. Q. Implanted thousands? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market? A. So I'm having a little difficulty even in my own practice anymore using polypropylene knowing that there's a chronic foreign body reaction, knowing that polypropylene degrades. I don't know how I'm going to personally deal with that. I'm	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am. Q. Have for 13 years? A. Yes. Q. Implanted thousands? A. Yes. Q. Have you ever told any of your patients that you shouldn't have used polypropylene because of its deterioration or
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market? A. So I'm having a little difficulty even in my own practice anymore using polypropylene knowing that there's a chronic foreign body reaction, knowing that polypropylene degrades. I don't know how I'm going to personally deal with that. I'm going to have come up with an alternative	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am. Q. Have for 13 years? A. Yes. Q. Implanted thousands? A. Yes. Q. Have you ever told any of your patients that you shouldn't have used polypropylene because of its deterioration or foreign body reaction propensities?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Yeah. Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery? A. Plus everything that I've read to date. Q. What is it that you've read to date specifically that or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market? A. So I'm having a little difficulty even in my own practice anymore using polypropylene knowing that there's a chronic foreign body reaction, knowing that polypropylene degrades. I don't know how I'm going to personally deal with that. I'm going to have come up with an alternative source. Maybe going to completely cadaver	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Not like polypropylene. Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara? A. Yes. Q. And they're subject to chronic foreign body reaction? A. Yes. Q. They're subject to deterioration? A. Yes. Q. You're still using them? A. I am. Q. Have for 13 years? A. Yes. Q. Implanted thousands? A. Yes. Q. Have you ever told any of your patients that you shouldn't have used polypropylene because of its deterioration or
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	Page 86		Page 88
1	Q. And you started that a year or	1	in a thousand, one in 22,000.
2	so ago?	2	Q. With your technique?
3	A. Yes.	3	A. With my technique.
4	Q. What problems does the chronic	4	But it's not 10, 12 percent.
5	foreign body reaction cause?	5	Q. So let me make sure, as I go
6	Let me withdraw that question	6	through these questions what I'm asking for
7	and ask something better.	7	is with the Desara or the Uretex, if you
8	You can have a chronic foreign	8	follow the manufacturer's instructions and
9	body reaction that doesn't cause any symptoms	9	you use the manufacturer's technique.
10	to the patient, true?	10	A. Okay.
11	A. I'm sure you can to some	11	Q. That's the premise.
12	extent, yes.	12	A. Okay.
13	Q. And are you aware of any	13	Q. All right. So can you have
14	studies that have shown that a chronic	14	acute and chronic pain with Desara and
15	foreign body reaction causes problems for	15	Uretex?
16	patients?	16	A. Following the manufacturer's
17	A. Yes.	17	technique, yes.
18	Q. What is that?	18	Q. Can you have acute and chronic
19	A. The problem is that it	19	pain with intercourse with Desara and Uretex?
20	contracts. The chronic foreign body reaction	20	A. Yes.
21	and the a lot because of the pore size it	21	Q. Can you have vaginal scarring
22	creates this granuloma-type of effect and	22	with Uretex and Desara?
23	entraps little nerves. Instead of the pores	23	A. Yes.
24	being far apart and the nerves being padded	24	Q. Can you have infection?
	Page 87		Page 89
1	with fat infiltration, the nerve gets	1	Let me is infection a risk
2	squeezed over time and that chronic	2	with surgery using Uretex and Desara?
3	inflammation continues to contract and it	3	A. Yes.
4	creates contraction in the vagina. So when	4	Q. Are urinary problems such as
5	you examine these patients, you feel a	5	urinary frequency, urgency, dysuria,
6	tethering effect like a banjo string or a	6	retention, obstruction and incontinence, are
7	rope, and that causes pain.	7	those potential risks with Desara and Uretex?
8	Q. Do you have acute or chronic	8	A. Yes.
9	pain with Desara and Uretex slings?	9	Q. Organ and nerve damage, are
10	A. Can you? Yes.	10	those potential risks with Desara and Uretex?
11	Q. That's a risk?	11	A. Yes.
12	A. Yes.	12	Q. Postoperative bleeding, is that
13	Q. And acute or chronic pain with	13	a potential risk with Uretex and Desara?
14	intercourse, is that a risk of SUI surgery	14	A. Yes.
15	with Uretex or Desara?	15	Q. Wound complications, is that a
16	A. Can I qualify the answer?	16	potential risk with Desara and Uretex?
17	Q. You can say yes first and then	17	A. Yes.
1 ^	1:0		Q. Inflammation, is that a
18	qualify.	18	
19	A. Yes, you can, but that's	19	potential risk?
19 20	A. Yes, you can, but that's because they follow the manufacturer's	19 20	potential risk? A. Yes.
19 20 21	A. Yes, you can, but that's because they follow the manufacturer's instructions and don't do exactly what I do.	19 20 21	potential risk? A. Yes. Q. Fistula formation, is that a
19 20 21 22	A. Yes, you can, but that's because they follow the manufacturer's instructions and don't do exactly what I do. In my patients, it's basically,	19 20 21 22	potential risk? A. Yes. Q. Fistula formation, is that a potential risk with Uretex and Desara?
19 20 21 22 23	A. Yes, you can, but that's because they follow the manufacturer's instructions and don't do exactly what I do. In my patients, it's basically, no, it doesn't happen.	19 20 21 22 23	potential risk? A. Yes. Q. Fistula formation, is that a potential risk with Uretex and Desara? A. Yes.
19 20 21 22	A. Yes, you can, but that's because they follow the manufacturer's instructions and don't do exactly what I do. In my patients, it's basically,	19 20 21 22	potential risk? A. Yes. Q. Fistula formation, is that a potential risk with Uretex and Desara?

23 (Pages 86 to 89)

	Page 90		Page 92
1	pelvic floor muscles, is that a potential	1	understand them.
2	risk with Uretex and Desara?	2	Q. This is mesh that's been in the
3	A. Yes.	3	body?
4	Q. Lower extremity pain, is that a	4	A. No. No. No.
5	potential risk?	5	Q. Okay.
6	A. No.	6	A. Expired, donated from reps.
7	Q. Abdominal pain, is that a	7	Q. Okay. Have you seen any mesh,
8	potential risk?	8	TVT® mesh, falling apart in the body?
9	A. Yes.	9	A. Yes. Yes.
10	Q. Need for additional surgery, is	10	Q. In your explanting procedures?
11	that a potential risk with Uretex and Desara?	11	A. Yes.
12	A. Yes.	12	Q. And if I asked this, I
13	Q. Failure of the procedure, is	13	apologize.
14	that a potential risk with Uretex and Desara?	14	Can you point me to any medical
15	A. Yes.	15	literature where someone has described a
16	Q. Foreign body reaction is a	16	problem with the TVT® mesh falling apart as
17	potential risk, chronic foreign body reaction	17	you describe it?
18	with Uretex and Desara?	18	A. You mean the fraying?
19	A. Yes.	19	Q. I mean, the falling you said
20	Q. Exposure or erosion or	20	that it falls apart.
21	extrusion, is that a potential risk with	21	I want to know has anybody
22	Desara and Uretex?	22	written a medical paper that has said, you
23	A. Yes. Again, all of those	23	know, this TVT® mesh falls apart when it gets
24	following the manufacturer's instructions for	24	in the body.
	Page 91		Page 93
1	implantation.	1	Have you read that anywhere?
2	Q. And contraction or shrinkage of	2	A. I can't recall.
3	tissues, is that a potential risk with Uretex	3	Q. You can't point me to anything?
4	and Desara?	4	A. I cannot at this time, no.
5	A. Yes.	5	Q. And it's certainly not in your
6	Q. All right. Now, do you have	6	report, true?
7	any opinion as to what the relative risks are	7	A. No.
8	of those things we went through for TVT®	8	Q. True?
9	versus Uretex and Desara slings?	9	A. True.
10	A. Following the manufacturer's	10	Q. So your only basis for saying
11	instructions?	11	that in the body the TVT® mesh frays so badly
12	Q. Yes.	12	that it falls apart is what you've seen from
13	A. Okay. They're slightly higher	13	your explant procedures, true?
14	for TVT® because of the weave design of the	14	A. Yes.
15	mesh that upon any traction it frays and	15	Q. Are there any samples of that
16	literally falls apart.	16	in your report?
17	Q. This falling apart, have you	17	A. No.
18	actually seen it fall apart?	18	Q. Do you have any if we want
1.0	A. Oh, yes.	19	to say, I don't know, I've never seen such a
19		20	thing, I've never heard of such a thing, we
20	Q. This is in your surgeries you	40	uning, i to no tel mealer of barell a uning, the
	Q. This is in your surgeries you do?	21	
20			wanted to see it, what do you do?
20 21	do?	21	wanted to see it, what do you do? A. I have pictures.
20 21 22	do? A. No, I have samples of mesh that	21 22	wanted to see it, what do you do? A. I have pictures.

Page 94 Page 96 1 Yes. 1 that causes this fraying and falling apart A. 2 2 problem is the way it's cut on the edges, is Q. Okay. 3 Lots of pictures. that what you're saying? 3 A. 4 4 And these are -- this is mesh A. Yes. And that's why it went to 5 falling apart, not as a result of you taking 5 laser cut afterwards. 6 6 it out? Q. Does the laser cut have the 7 7 same problem? A. No. 8 8 O. Why do you think nobody else A. To a less extent. 9 has ever written about that? 9 Okay. So is the laser-cut 10 10 A. I don't know. I haven't mesh, do the risks of that outweigh the benefits so that it never should have been 11 written about it. 11 12 O. Okay. So other than this 12 put on the market? 13 13 tenancy -- and the reason you think it frays A. Yes. and falls apart is because the edge -- tell 14 14 Q. Okay. For what reason? 15 me why you think the TVT® frays and falls 15 It's the same thing. The 16 apart as you describe it and the other ones 16 elasticity. It still pops apart where the 17 laser seals it a little bit, but if you put 17 don't. 18 18 traction on it, it pops apart. A. It has to do with the weave. 19 Q. Okav. 19 Q. So the problem you have -- I've 20 heard two problems you have with the mesh 20 So when TVT® was mechanically 21 itself. We've talked about the 21 cut early on it was clear before they made it blue, it was harder to see it. But when it 22 instrumentation issue, and we've talked about 22 23 became blue, it became very visible in the 23 the technique. tissues. I have a clear recollection from 24 24 A. Yes. Page 95 Page 97 1 years ago on a slide where I'm not removing Q. The mesh itself, what I've 2 the sling, but I'm fixing the woman's 2 heard, is that you have two criticisms of the 3 prolapse after she had her sling and have the 3 TVT® mesh: One is whether it's mechanically 4 vaginal wall open and you can see a hairpin 4 cut or laser cut, the edges are -- or the 5 5 loop of mesh attached in there. weave and the edges are susceptible to 6 I probably wouldn't have seen 6 fraying and falling apart in the body, that's 7 that when it was clear. I did see it when it 7 one, right? 8 8 was clear when I first handled it early on. 9 O. So --9 And then number two, the pores, 10 A. So it has to do -- you know, 10 once they're in the body, are not big enough 11 this mesh starts as a suture, and then it 11 to allow the tissue ingrowth? 12 goes through a machine that knits it into a 12 A. Yes. 13 big sheet, and then it gets cut. 13 And three, and this applies to 14 So TVT® and the Boston 14 all polypropylene, including the 15 Scientific product are somewhat similar in 15 polypropylene I'm implanting, was not very 16 the fact that when you first cut the TVT® 16 clear when this all came out, when this 17 early on when it was mechanically cut, the 17 product first came out, that polypropylene 18 edges would fray. It was sort of like 18 degrades. 19 cutting a sweater that your grandma knit and 19 Q. Now, are you aware of any 20 you got a cut and it started to unfray, but 20 medical literature where someone has 21 it wasn't on the body like a sweater. It's a 21 identified degradation of TVT® polypropylene 22 strip of mesh so when you cut it and you pull 22 as causing clinical problems for patients? on it, they would pop off. 23 23 A. Well, the Clavé study looked at 24 Q. So the problem with the weave 24 polypropylene TVT® and studied that that

	Page 98		Page 100
1	causes contraction and fibro a chronic	1	complications?
2	inflammation and scarring and shortening and	2	A. Yes.
3	shrinkage and possibly erosion.	3	Q. Potential complications?
4	Q. So your interpretation of the	4	A. Yes.
5	Clavé paper is that it says that degradation	5	Q. Which ones?
6	of TVT® polypropylene produces clinical	6	A. Cording, roping, because of the
7	problems for patients?	7	fraying that occurs and loss of fibers.
8	A. Yes.	8	Q. Okay. And then what
9	Q. All right. Any other paper	9	complication does that cause for the patient?
10	besides that?	10	A. Retention. It can cause pelvic
11	A. With TVT®?	11	pain. It can cause exposure, erosion.
12	Q. Yes.	12	Q. Okay. Do you have an opinion
13	A. Not that I recall off the top	13	as to whether the rate of exposure and
14	of my head.	14	erosion with TVT® is higher or lower or the
15	Q. Okay. Now I'm going to broaden	15	same as compared to Uretex and Desara?
16	it. You anticipated that.	16	A. I don't see many patients that
17	Are you aware of any papers	17	have a Desara problem. I see very few
18	that say polypropylene in general in use with	18	patients that have a Uretex problem. I do
19	vaginal surgery degrades to such an extent	19	see many patients with TVT® problem.
20	that it causes clinical problems for	20	Q. Do you have any notion as to
21	patients?	21	how many TVT®s have been implanted versus
22	A. All mesh, or mesh in general,	22	Desara and Uretex?
23	right?	23	A. I'm sure there's a lot more
24	Q. Yes.	24	TVT®s.
	Q. 103.		1,100.
	Page 99		Page 101
1	A. Yeah.	1	Q. Right.
2	I am. Let me refresh my	2	So it's not really fair to
3	memory.	3	compare numbers of problems you see with
4	Q. Let me ask this.	4	Desara and Uretex versus TVT®, true?
5	A. Yes.	5	A. Sure. Yes.
6	Q. Do you cite any paper in either	6	Q. Okay. Are you aware of any
7	of your reports, Exhibits 2 or 3, concerning	7	study that says that TVT® with respect to any
8	TVT® or Gynemesh® that to support the	8	of the complications of the potential
9	proposition that polypropylene degrades and	9	complications of SUI surgery with mesh has a
10	causes clinical problems for patients?	10	greater propensity for any of these
11	A. I don't know that there's any	11	
	A. I don't know that there's any	1	calculations than compenior products?
12	•		calculations than competitor products? A. That study hasn't been done.
12 13	papers that say there's clinical problems.	12	A. That study hasn't been done.
13	papers that say there's clinical problems. Q. Okay. Now, by the way, how	12 13	A. That study hasn't been done.Q. And do you have an opinion
13 14	papers that say there's clinical problems. Q. Okay. Now, by the way, how many hours did you spend just preparing for	12 13 14	A. That study hasn't been done.Q. And do you have an opiniondo you believe you have sufficient
13	papers that say there's clinical problems. Q. Okay. Now, by the way, how many hours did you spend just preparing for this deposition?	12 13 14 15	 A. That study hasn't been done. Q. And do you have an opinion do you believe you have sufficient information to state an opinion as to the
13 14 15 16	papers that say there's clinical problems. Q. Okay. Now, by the way, how many hours did you spend just preparing for this deposition? A. 20.	12 13 14 15 16	A. That study hasn't been done. Q. And do you have an opinion do you believe you have sufficient information to state an opinion as to the comparative risks of TVT® versus Uretex and
13 14 15 16 17	papers that say there's clinical problems. Q. Okay. Now, by the way, how many hours did you spend just preparing for this deposition? A. 20. Q. Okay. We went through a long	12 13 14 15 16 17	A. That study hasn't been done. Q. And do you have an opinion do you believe you have sufficient information to state an opinion as to the comparative risks of TVT® versus Uretex and Desara with respect to any of these
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than there have been Desarr and Uretex, true? 3		Page 102		Page 104
than there have been Desara and Uretex, true? A. Yes. Q. Okay. 10 or 20 times as many, right? A. I wouldn't know. A. I wouldn't know. A. I wouldn't know. B. Desara or any other type of polypropylene sling? A. Not at this time. Q. Okay. So do you believe you have a rudil descintific basis to state that the complications with TVT® are greater than Uretex and Desara? Leve and Desara? Q. Okay. And what is that secientific basis? Leve and Desara and Uretex and D	1	far more TVT®s implanted in the population	1	wasn't clear, and I'll make it.
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think do you have any estimate as to what percentage of patients with TVT® simple have any estimate as to what percentage of patients with TVT® simple had problems with long-term inflammation? A Yes. A Ask this again, please. Q Do you have any and I think let me just ask a global question. You list in your report at page 5 okay, let's go to your report, your TVT® report, page 5. A Ask this again, please. Q Do you have any and I think let me just ask a global question. You list in your report at page 5 okay, let's go to your report, your TVT® report, page 5. Okay. Paragraph A, under the list of opinions, right? A Yes. Q And you see you say the mesh in TVT® can cause foreign body reaction, inflammation, et cetera. Do you see that? Page 103 Page 105 Page 105 Page 105 Page 105 A Yes. Q Okay. Do you have any estimate as to what percentage of patients with Ony-term inflammation? A Ask this again, please. Q Do you have any and I think dre page 5 okay, let's go to your report, your TVT® report, page 5. Okay. Paragraph A, under the list of opinions, right? A Yes. Q And you see you say the mesh in TVT® can cause foreign body reaction, inflammation, et cetera. Do you see that? Page 105 A Yes. Q Okay. Do you have any opinion as to what percentage of the patients Wo have for the patients who have had a TVT® implanted have problems of chronic foreign body reaction, inflammation, fibrotic bridging, mesh contraction, fraying, particle loss? A A It of the patients I see in my practice. Q In your explant practice? A Yes. Q Is appreciate that, but my question was of all of the people that have had them implanted, do you have an opinion as to what percentage have had any of those problems? A I am sorry. A I am sorry. A I am sorry. A I have a guesstimate. Q Okay. A I have a guesstimate. Q I'll hear it even though I don't think it's admissible, but go ahead. A 30 percent. Q And you see you say the mesh in TVT® can cause foreign body reaction, inflammation, for the patients who have had a T				
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	Page 106		Page 108
1	polypropylene mesh that it shrinks 20 to	1	not it's not very precise.
2	40 percent. So about 30. So about	2	Q. Did you read the IFU before you
3	30 percent of those patients are going to	3	implanted the TVT® a number of years ago?
4	have a problem.	4	A. Yes.
5	Q. What's that 20 to 40 percent	5	Q. Do you believe that experienced
6	shrinkage rate based on?	6	surgeons who perform SUI surgery with mesh in
7	Is that in vivo or ex vivo?	7	2010 and before were aware that a potential
8		8	complication was acute or chronic pain?
9		9	A. I don't think they knew about
10	not in vivo in patients.	10	•
11	Q. So do you have any data that	11	it, no. O. What about acute or chronic
12	talks about the shrinkage rate of mesh, of a		Ç
	TVT® mesh, in a woman?	12	pain with intercourse?
13	A. No.	13	A. No, I don't think they knew
14	Q. And a woman can have foreign	14	about it.
15	body reaction and have no symptoms, true?	15	Q. So you don't think experienced
16	A. Some might, yes.	16	surgeons before 2010 knew that acute or
17	Q. A woman can have fibrotic	17	chronic pain with intercourse was a possible
18	bridging and have no symptoms, true?	18	complication with mesh SUI surgery?
19	A. I haven't seen any.	19	A. May I ask what would you call
20	Q. I didn't ask whether you've	20	an experienced surgeon?
21	seen any.	21	Q. Somebody that does sling
22	Can that occur?	22	surgery on a regular basis.
23	A. I haven't seen everyone. I	23	A. I don't know what a regular
24	want to be truthful and precise, but just as	24	basis once a week?
	Page 107		Page 109
1			
1	I don't know	1	Q. You can't answer the question?
2	I don't know Q. Well, there's varying degrees	1 2	Q. You can't answer the question?A. No. I'm trying to ascertain
			•
2	Q. Well, there's varying degrees	2	A. No. I'm trying to ascertain
2	Q. Well, there's varying degrees of fibrotic bridging, aren't there?	2	A. No. I'm trying to ascertain what a I don't think an experienced
2 3 4	Q. Well, there's varying degreesof fibrotic bridging, aren't there?A. I think fibrotic bridging is	2 3 4	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I
2 3 4 5	 Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as 	2 3 4 5	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone
2 3 4 5 6	Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas.	2 3 4 5 6	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I,
2 3 4 5 6 7	 Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas. Q. Are there varying degrees of 	2 3 4 5 6 7	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings,
2 3 4 5 6 7 8	 Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas. Q. Are there varying degrees of mesh contracture? 	2 3 4 5 6 7 8	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings, wouldn't have thought that a patient would
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2 3 4 5 6 7 8 9	Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas. Q. Are there varying degrees of mesh contracture? A. It can vary, 20, 30, 40 percent.	2 3 4 5 6 7 8 9	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings, wouldn't have thought that a patient would have had pain with intercourse from a polypropylene sling.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas. Q. Are there varying degrees of mesh contracture? A. It can vary, 20, 30, 40 percent. Q. Down here in opinion C, Ethicon failed to adequately describe to physicians how to properly tension the TVT®. Does this go back to the technique criticisms you had? A. That's actually in the IFU. In	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings, wouldn't have thought that a patient would have had pain with intercourse from a polypropylene sling. And I saw many patients that went to their doctors and all they heard was a common phrase, "It's not the mesh, it's not the mesh, it's not the mesh." So the examination has to be very specific and precise on where the mesh is placed. And
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Well, there's varying degrees of fibrotic bridging, aren't there? A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas. Q. Are there varying degrees of mesh contracture? A. It can vary, 20, 30, 40 percent. Q. Down here in opinion C, Ethicon failed to adequately describe to physicians how to properly tension the TVT®. Does this go back to the technique criticisms you had? A. That's actually in the IFU. In the IFU in one place it says, "minimal tension," and in one place it says, "no tension." It talks about doing the placement under a local or under a general. Under local at 300 MLs they're supposed to cough until there's a drop. So that is a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No. I'm trying to ascertain what a I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings, wouldn't have thought that a patient would have had pain with intercourse from a polypropylene sling. And I saw many patients that went to their doctors and all they heard was a common phrase, "It's not the mesh, it's not the mesh, it's not the mesh, it's not the mesh is placed. And when you do that and you listen to these women, you see that that is the cause, confirmed by my own removal and their pain goes away. Q. Was pain with intercourse a risk with Mersilene?

Page 110 Page 112 1 Knowing what I know today, 1 along, it changed the mindset of everyone. 2 probably. But it's a lot softer. It's 2 You don't need to harvest. You don't need to 3 3 lightweight. It's 33 grams per meter take the extra time in the OR. This is quick squared. It's not 100. This lays very flat. 4 4 and easy. Here you go. It's a whole kit; 5 You can't feel it so it drastically less. 5 put it in. The report by Ulmsten was you 6 Q. Is pain with intercourse a risk 6 could do this in 25 minutes under local. The 7 7 with the Burch procedure or the MMK patient goes home the same day. It all 8 8 procedure? sounded really, really good, and a lot of 9 9 people abandoned doing autologous slings. A. No. 10 10 0. Paragraph E, Ethicon failed to Q. As far as you understand, the 11 inform physicians of certain patient 11 Desara sling is safe? 12 populations may be more prone to experience 12 A. The way I use it, yes. adverse outcomes or higher frequency or It's not safe if you follow 13 13 manufacturer's instructions? 14 severity of risk. 14 15 What patient populations fall 15 A. No. 16 into that category? 16 And the Uretex sling was safe 0. in your technique, but not using 17 A. Patients that have excessive 17 18 scarring, and you don't know who that is, but 18 manufacturer's instructions? 19 there are patients that formed keloids, for 19 A. Correct. 20 example. 20 Q. Okay. So down here in 21 paragraph F where you say that there were The only warning is in patients 21 that are growing or pregnant are going to safer alternative options available, what 22 22 23 have a delivery. So patients that are on 23 available options were safer? steroids, patients who are diabetic, women 24 24 A. Burch, autologous slings, Page 111 Page 113 1 that have chronic obstructive lung disease, 1 cadaveric slings. 2 elderly women that may not heal right. A 2 Q. Do you still offer patients certain percentage of smokers. 3 Burch as an alternative if you're not going 3 Q. Those are all ones that should 4 to be doing an abdominal surgery? 4 5 5 not have --A. I do. 6 6 Has anyone chosen that? A. Those are ones that ought to be Q. 7 warned that they may have a higher frequency 7 One patient. A. 8 So as you're sitting here 8 of complications. Autologous and cadaveric 9 today, do you believe a Burch procedure is a 9 10 safer procedure for a patient than any type 10 slings, have they always been available for of mesh sling procedure? 11 SUI? 11 12 A. Long term, yes. 12 A. Autologous sling was actually 13 described in 1907 by Von Giordano was 13 Okay. And do you believe 14 autologous and cadaveric slings are safer actually an autologous sling. 14 15 procedures than any kind of mesh? 15 Q. Yeah, I don't want to go back 16 16 quite that far. A. Yes. 17 17 Q. Do you tell your patients that, Have they been in regular use do you tell your patients that long -- when 18 18 for how long? 19 you're having this discussion with them and 19 A. I think they were really giving the alternatives, do you tell your 20 popularized in the '40s by Aldridge. 20 21 patients that you can either have a mesh 21 Q. So in the 2000s, were doctors sling, or you can have an autologous sling, 22 22 regularly performing sling procedures with 23 or you can have a cadaveric sling, or you can 23 cadavers and autologous grafts? 24 A. I think that when TVT® came 24 have a Burch procedure?

29 (Pages 110 to 113)

	Page 114		Page 116
1	Those are your four	1	SUI, all these other procedures, are safer
2	alternatives, right?	2	than any type of mesh sling?
3	Is that right?	3	A. No, there's literature that
4	A. And some urethral plication.	4	says there's alternatives. I don't know that
5	Q. And what is that, briefly?	5	anyone has done a head-to-head comparison
6	A. Briefly, it's the pubourethral	6	long term for these procedures the way that
7	ligaments that are replaced by TVT®, which is	7	they do surgery.
8	the theory of Ulmsten and Papa Petros.	8	When I'm counseling my
9	Instead of replacing them with an implant,	9	patients, it's the way that I do surgery and
10	you grasp them and you suture them underneath	10	even the polypropylene slings that I place, I
11	the midline and create a in-situ sling.	11	do differently.
12	Q. So it's kind of a native tissue	12	Q. My question is are you aware of
13	repair, so to speak?	13	any literature, scientific, published
14	A. You could call it that, yes.	14	literature, that says that mesh slings are
15	Q. It's not using any kind of	15	the least a safe alternative for SUI surgery
16	outside material?	16	long term?
17	A. Correct.	17	A. No.
18	Q. Okay. So that's the fifth one	18	Q. Okay. In fact, are you a
19	you offer?	19	member of any organizations?
20	A. Yes, if their urodynamics are	20	A. Yes.
21	not severe incontinence.	21	Q. What?
22	Q. And do you believe that's a	22	A. ACOG, Society of Gynecologic
23	safer alternative than any type of mesh?	23	Surgeons, AUGS, AAGL.
24	A. That is the safest, yes.	24	Q. Do any of those organizations
	·		, ,
	Page 115		Page 117
1	Page 115 Q. Okay. So when you're sitting	1	Page 117 publish guidelines or practice parameters or
1 2		1 2	
	Q. Okay. So when you're sitting		publish guidelines or practice parameters or
2	Q. Okay. So when you're sitting there talking to a patient and you're giving	2	publish guidelines or practice parameters or position statements about SUI surgery?
2 3	Q. Okay. So when you're sitting there talking to a patient and you're giving them these five alternatives, do you tell	2 3	publish guidelines or practice parameters or position statements about SUI surgery? A. I think AUGS and SUFU has put
2 3 4	Q. Okay. So when you're sitting there talking to a patient and you're giving them these five alternatives, do you tell them that all of the alternatives are safer	2 3 4	publish guidelines or practice parameters or position statements about SUI surgery? A. I think AUGS and SUFU has put something out there.
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2 3 4 5 6 7	Q. Okay. So when you're sitting there talking to a patient and you're giving them these five alternatives, do you tell them that all of the alternatives are safer long term than a mesh procedure? A. I tell them that I don't know what the long-term complications from a sling	2 3 4 5 6 7	publish guidelines or practice parameters or position statements about SUI surgery? A. I think AUGS and SUFU has put something out there. Q. And do either of those publications state that mesh surgery is the gold standard for SUI treatment?
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	Page 118		Page 120
1	of, does not mean that it's the preferred	1	A. It says that, yes.
2	procedure?	2	Q. And number two, do you agree
3	A. That's not what it means to me.	3	with that statement?
4	I've seen I remember looking at that and	4	A. I do not.
5	calling it the gold standard and years ago	5	Q. And because?
6	the Burch was the gold standard and the	6	A. Because they're talking about
7	sacrocolpopexy is the gold standard. And	7	two completely different types of midurethral
8	what I've always taken that to mean is when	8	slings. So first is the retropubic TVT®, and
9	what I ve always taken that to mean is when we treat women across the country, across the	9	the second is the TOT. So if you lump those
10	•	10	· · · · · · · · · · · · · · · · · · ·
11	planet, that the procedures that we do in the	11	two together, those are completely different
12	hands of many are safe, which is what this		slings even though they're multi-incision.
	data is supposed to extrapolate and tell us,	12	They have a completely different set of cure
13	the risk/benefit ratio. So that if someone	13	and complication profiles.
14	who is a very good scientist does a very	14	Q. And you believe that the
15	well-designed study and comes up with a	15	obturator slings are less safe than the
16	percentage of cure, that that would then	16	retropubic?
17	extrapolate to the hands of other surgeons.	17	A. If we define how do we
18	Q. Do you believe that mesh sling	18	define safe? Bladder perforation, they have
19	surgery is the gold standard for the	19	less bladder perforations. They have
20	treatment of SUI?	20	Q. Overall safety.
21	A. I believe slings are the gold	21	A. Overall safety?
22	standard.	22	Q. And efficacy.
23	Q. That wasn't my question.	23	A. They are less efficacious.
24	A. I know.	24	They're safer in the sense that you don't
	Page 119		Page 121
1		1	
	Q. My question is do you believe		enter the pelvic bowl and you injure
2	Q. My question is do you believe that mesh slings are the gold standard for	1 2 3	enter the pelvic bowl and you injure structures, but they have their own unique
2 3	Q. My question is do you believe that mesh slings are the gold standard for well, strike that.	2 3	enter the pelvic bowl and you injure structures, but they have their own unique set of problems with the leg pain, as you
2 3 4	Q. My question is do you believe that mesh slings are the gold standard for well, strike that. The AUGS does say that mesh	2 3 4	enter the pelvic bowl and you injure structures, but they have their own unique set of problems with the leg pain, as you mentioned in one of your questions, with limb
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2 3 4 5 6	Q. My question is do you believe that mesh slings are the gold standard forwell, strike that. The AUGS does say that mesh slings are the gold standard for treatment of SUI, true?	2 3 4 5 6	enter the pelvic bowl and you injure structures, but they have their own unique set of problems with the leg pain, as you mentioned in one of your questions, with limb pain as it transverses the obturator muscles and the adductors.
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	Page 122		Page 124
1	being placed the way that the company	1	often talk about mechanically cut mesh can
2	suggested it be placed.	2	fray, et cetera, and release particles.
3	Q. Do you classify the TVT® mesh	3	Do you have anywhere in your
4	pore size as macroporous or microporous?	4	report that you refer to laser-cut mesh
5	A. It's less than 1 millimeter, so	5	having that same issue?
6	it's micro.	6	A. Which issue was that? The
7	Q. In the body or outside the	7	fraying?
8	body?	8	Q. Like on page 9 you say the
9	A. Inside the body.	9	mechanically cut mesh was known to rope, curl
10	Q. Okay. So under the Amid	10	and deform, and the mechanically cut version
11	classification, are the measurements made	11	of mesh could fray or release particles.
12	inside of the body or outside the	12	Do you have anywhere in your
13	classification?	13	report where you say laser-cut mesh can rope,
14	A. Amid classification is 75	14	curl or deform or release particles?
15	microns. Everything is macroporous by that	15	A. Well, I didn't specifically
16	definition.	16	state that, but it's implied.
17	Q. So are you aware of any	17	Q. How is it implied?
18	classification system other than the Amid	18	A. Well, just because it's laser
19	system for classifying pore size in mesh?	19	cut doesn't mean it's not going to fray.
20	A. No.	20	Q. Do you say that in here
21	Q. All right. Under that	21	anywhere?
22	classification, the mesh in TVT® is	22	I see where you specifically
23	macroporous?	23	say the mechanically cut mesh will fray and
24	A. Yes.	24	have particle loss, et cetera.
21	A. 105.		have particle loss, et ectera.
	Page 123		Page 125
1	Page 123 Q. Right?	1	Page 125 Did you ever say laser-cut mesh
1 2		1 2	
	Q. Right?		Did you ever say laser-cut mesh
2	Q. Right? Okay. How did you decide which	2	Did you ever say laser-cut mesh will do that?
2 3	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and	2 3	Did you ever say laser-cut mesh will do that? A. I may have been remiss in
2 3 4	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your	2 3 4	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that.
2 3 4 5	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands	2 3 4 5	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that?
2 3 4 5 6	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all,	2 3 4 5 6	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes.
2 3 4 5 6 7	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands	2 3 4 5 6 7	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes. Q. When you take a when you
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands of pages of testimony from Ethicon employees? A. I would believe so. Q. There would be millions of pages produced from Ethicon? A. I wouldn't doubt it. Q. And in your report, you cited a few pieces of testimony and cited several documents, right? A. Yes. Q. How did you decide which pieces	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes. Q. When you take a when you explant a TVT®, are you able to tell whether it is laser cut or mechanically cut? A. I can tell before because I have the implant log. Q. Does the implant log specify mechanical cut versus laser cut? A. It does. Q. It says it on there? A. Uh-huh. 810081 BL. Q. That's the part number or
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands of pages of testimony from Ethicon employees? A. I would believe so. Q. There would be millions of pages produced from Ethicon? A. I wouldn't doubt it. Q. And in your report, you cited a few pieces of testimony and cited several documents, right? A. Yes. Q. How did you decide which pieces of testimony to cite and what not to cite and which documents to cite and what not to cite? A. I cited every I gathered	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes. Q. When you take a when you explant a TVT®, are you able to tell whether it is laser cut or mechanically cut? A. I can tell before because I have the implant log. Q. Does the implant log specify mechanical cut versus laser cut? A. It does. Q. It says it on there? A. Uh-huh. 810081 BL. Q. That's the part number or whatever? A. Yes. I am sorry, 41. 810041. The 81 is the TOT.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands of pages of testimony from Ethicon employees? A. I would believe so. Q. There would be millions of pages produced from Ethicon? A. I wouldn't doubt it. Q. And in your report, you cited a few pieces of testimony and cited several documents, right? A. Yes. Q. How did you decide which pieces of testimony to cite and what not to cite and which documents to cite and what not to cite? A. I cited every I gathered everything that I thought was relevant from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes. Q. When you take a when you explant a TVT®, are you able to tell whether it is laser cut or mechanically cut? A. I can tell before because I have the implant log. Q. Does the implant log specify mechanical cut versus laser cut? A. It does. Q. It says it on there? A. Uh-huh. 810081 BL. Q. That's the part number or whatever? A. Yes. I am sorry, 41. 810041. The 81 is the TOT. Q. I think you mentioned 34 TVT®s
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Right? Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report? Let me back up. First of all, are you aware that there have been thousands of pages of testimony from Ethicon employees? A. I would believe so. Q. There would be millions of pages produced from Ethicon? A. I wouldn't doubt it. Q. And in your report, you cited a few pieces of testimony and cited several documents, right? A. Yes. Q. How did you decide which pieces of testimony to cite and what not to cite and which documents to cite and what not to cite? A. I cited every I gathered everything that I thought was relevant from what was sent to me and cited it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Did you ever say laser-cut mesh will do that? A. I may have been remiss in saying that. Q. You mean in not saying that? A. Not saying that, yes. Q. When you take a when you explant a TVT®, are you able to tell whether it is laser cut or mechanically cut? A. I can tell before because I have the implant log. Q. Does the implant log specify mechanical cut versus laser cut? A. It does. Q. It says it on there? A. Uh-huh. 810081 BL. Q. That's the part number or whatever? A. Yes. I am sorry, 41. 810041. The 81 is the TOT. Q. I think you mentioned 34 TVT®s you removed last year?

1 TVT®s or just the TVT® that's the subject of 2 your report here? 3 A. Just the subject of my report. 4 Q. So TVT-Os and Abbrevos and 4 Q. So TVT-Os and Abbrevos and 5 whatever else would be on top of that? 5 A. That's different, yes. 7 Q. Of that 34, can you tell how many laser cur? 9 cur? 10 A. Yes, but I didn't separate them 10 out. 11 out. 12 Q. But just so we're clear, is it 29 your testimony that the laser-cut mesh never should have been sold either? 14 A. Yes. 15 Q. The Desara and Uretex, were 16 Q. The Desara and Uretex, were 17 those laser cut or mechanically curl? 18 A. They're not - they're neither. 19 Q. Oxay. And do you ever have to 20 cut a Desara to create exposed edges, a 21 Desara and a Uretex? 21 A. No, just after implantation, 4 for patients? 22 A. No, just after implantation, 5 for patients? 3 deepar that is above the skin, that's the 24 only cut. Page 127 1 Q. Can you point me to any 2 scientific literature that says that particle 3 loss with mesh causes any clinical problems for patients? 4 A. No. 1 my patient that you believe some of their clinical problems were related to 20 particle loss from mesh? 10 particle loss from mesh? 11 A. Not in those words, no. 12 Q. Have you ever referred to 21 particle loss from mesh? 12 A. No tin those words, no. 12 Q. In fact, do you know whether 22 particle loss from TVT® mesh causes any clinical problems were related to 20 particle loss from mesh? 21 A. Not in those words, no. 20 Q. Okay. What's your basis for that? 22 A. It narrows the caliber, the 23 diameter of the mesh, because the actual and that have to the resh subtractions and page that agrees with that statement you've and they pray in the to they rain gabout fraying now. Okay. In talking about fraying now. Okay. Im talking about fraying now. Okay. Im talking about particle loss. I'm not talking about fraying now. Okay. I'm talking about particle loss. I'm not talking about fraying now. Okay. I'm talking about particle loss. I'm not talking about particle loss. I'm not talking about particle		Page 126		Page 128
2 your report here? 3 A. Just the subject of my report. 4 Q. So TVT-Os and Abbrevos and 5 whatever else would be on top of that? 6 A. Thars different, yes. 7 Q. Of that 34, can you tell how 8 many were mechanically cut and how many laser 9 cut? 10 A. Yes, but I didn't separate them 11 out. 12 Q. But just so we're clear, is it 13 your testimony that the laser-cut mesh never 14 should have been sold either? 15 A. Yes. 16 Q. The Desar and Uretex, were 17 those laser cut or mechanically cut? 18 A. They're not they're neither. 19 Q. Okay. And do you ever have to 20 cut a Desara of create exposed edges, a 21 Desara and a Uretex? 22 A. No, just after implantation, 23 the part that is above the skin, that's the 24 only cut. Page 127 Q. Can you point me to any 25 scientific literature that says that particle 3 loss with mesh causes any clinical problems 4 for particle loss from mesh? 11 A. No to it those words, no. 24 Q. Have you ever written in any 25 medical operative report or medical record 26 for any patient that you believe some of their clinical problems were related to particle loss in any way in any medical record for any patient that you believe some of their clinical problems were related to particle loss from TVT® mesh causes any solinical problems with patients? 15 A. Not in those words, no. 26 Q. Have you ever written in any aparticle loss in any way in any medical record for any patient? 27 A. Not in those words, no. 38 that don't do that. 4 Q. If a that don't do that. 4 Q. If a that don't do that. 5 do Kay. Thrat laking about particle loss. Im not alking about particle loss. Im not falk that that you mean by particle loss? 4 A. Yes. 4 Curby Q breaks off. That loses that don't be that they low accusable the actual weave defaul washed actually beaching off. 5 Is that what you mean by particle loss? 5 A. Well, they're almost one in the same. 5 A. Well, they're almost one in the actually beaching off	1	TVT®s or just the TVT® that's the subject of	1	its configured design. It's a design flaw.
4 Q. So TVT-Os and Abbrevos and 5 whatever else would be on top of that? 6 A. That's different, yes. 7 Q. Of that 34, can you tell how cut? 8 many were mechanically cut and how many laser cut? 9 cut? 10 A. Yes, but I didn't separate them 11 out. 12 Q. But just so we're clear, is it 13 your testimony that the laser-cut mesh never 14 should have been sold either? 15 A. Yes. 16 Q. The Desara and Uretex, were 17 those laser cut or mechanically cut? 18 A. They're not they're neither. 19 Q. Okay. And do you ever have to 10 cut a Desara to create exposed edges, a 11 Desara and a Uretex? 12 A. No, just after implantation, 12 the part that is above the skin, that's the 17 only cut. Page 127 1 Q. Can you point me to any 22 scientific literature that says that particle 3 loss with mesh causes any clinical problems 4 for patients? 4 A. No. 6 Q. Have you ever written in any 10 medical operative report or medical record 11 for any patient! 11 A. Not in those words, no. 12 Q. Have you ever referred to 13 particle loss from TVT® mesh causes any 14 clinical problems were related to 15 A. No. I fact, do you know whether 16 Q. In fact, do you know whether 17 particle loss from TVT® mesh causes any 18 clinical problems with patients? 19 A. No I fact, do you know whether 19 particle loss from TVT® mesh causes any 10 clinical problems with patients? 11 A. No I atth its time. 12 Q. Can you point me to anybody 12 clinical problems with patients? 14 C. The talking about raticlial loss. That laking about 15 hat what you mean by 16 lokay. The talking about is that what you mean by 16 lokay. The talking about is that what you mean by 17 medical operaticle so. 18 that what you mean by 19 anticle loss from the mesh is flawed. And because it's flawed, when you purticle one in the 12 dissimont particle loss in any way in any medical 14 record for any patient? 15 A. No. at the first plantation. 16 Q. In fact, do you know whether 17 particle loss from TVT® mesh causes any clinical problems with patients? 19 A. I do. Q. Okay. What's your bas	2	your report here?	2	
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24 weave unravers. when it unravers, it loses 24 paper that agrees with that statement you've	16 17 18 19 20 21 22	particle loss from TVT® mesh causes any clinical problems with patients? A. I do. Q. Okay. What's your basis for that? A. It narrows the caliber, the	17 18 19 20 21 22	Can you point me to anybody that has published something and agrees with that? A. I don't think that they've compared it to other slings.
	16 17 18 19 20 21 22 23	particle loss from TVT® mesh causes any clinical problems with patients? A. I do. Q. Okay. What's your basis for that? A. It narrows the caliber, the diameter of the mesh, because the actual	17 18 19 20 21 22 23	Can you point me to anybody that has published something and agrees with that? A. I don't think that they've compared it to other slings. Q. So you can't point me to any

	Page 130		Page 132
1	made, true?	1	A. No.
2	A. Not at this time.	2	Q. Have you ever said that to any
3	Q. True?	3	group of doctors about Gynemesh® PS?
4	A. Yes.	4	A. No.
5	MR. BALL: Okay. That's it.	5	Q. Why not?
6	We'll take a break.	6	A. Don't normally get in front of
7	(Off the record at 11:08 a.m.)	7	a group of doctors.
8	QUESTIONS BY MR. BALL:	8	Q. Well, I mean, you've presented
9	Q. Now, have you ever let me	9	abstracts five times in the last five years,
10	get to your CV here. You want to get that	10	right, according to your presented abstracts
11	out. I've got just a few questions about	11	in your CV?
12	that.	12	A. Which abstracts are you
13	It's attached, I think, to the	13	Q. Looking at part of your résumé
14	back of have you ever published anything	14	or your CV that says "Presented Abstracts."
15	specifically about TVT®?	15	The second page of your CV.
16	A. No.	16	A. So that first one was
17	Q. Have you ever published	17	sacrocolpopexy.
18	anything specifically about Gynemesh® PS?	18	Q. No. What I'm asking, did you
19	A. No.	19	actually go out there and present your
20	Q. Have you published anything	20	abstract?
21	about use of mesh in SUI surgery?	21	A. I did not present it.
22	A. I published a paper looking at	22	Q. On any of these first five that
23	the recommendation of a sling with SUI	23	were 2011 to the present, did you do the
24	diagnosis.	24	presentation?
	Page 131		Page 133
1	Q. Where was that published, or	1	A. I did not.
2	how long ago was that, let me ask that?	2	Q. Okay. So one of them is mesh
3	A. '95.	3	complications requiring removal of
4	Q. Have you ever published that	4	midurethral slings, oral presentation.
5	TVT® has all these problems and, therefore,	5	Did you do that?
6	should never have been sold?	6	A. Did not.
7	A. No.	7	Q. Did you participate in whatever
8	Q. Why not?	8	the materials were?
9	A. I've been busy taking care of	9	A. Yes.
10	people.	10	Q. Do you have those?
11	Q. Have you ever published that	11	A. What do you mean by materials?
12	Gynemesh® PS strike that. Let me back up.	12	Q. I assume when you make what
13	Do you believe Gynemesh® PS was	13	was the format of this oral presentation?
14	so poorly designed it never should have been	14	Let me back up. Why would you
15	sold?	15	be listed as giving an oral presentation in
16	A. Yes.	16	September of 2011 about mesh complications
17	Q. Have you ever published that	17	requiring removal of midurethral slings, if
18	opinion?	18	you didn't do it?
19	A. No.	19	A. I did do it. I was part of the
20	Q. Same reason?	20	project, but I was not the one verbally
0.1	A. Yes.	21	presenting the project.
21		22	Q. Were you there?
22	Q. Have you ever stated in any	l	
22 23	kind of presentation to other doctors that	23	A. No.
22		l	

34 (Pages 130 to 133)

	Page 134		Page 136
1	A. The project was looking at all	1	discussions did you say that TVT® or
2	the slings that had issues. It didn't single	2	Gynemesh® PS should never be used, true?
3	out TVT® at that time.	3	A. True.
4	Q. Was that published in some	4	Q. And there's no written
5	manner?	5	materials for those roundtable discussions?
6	A. No.	6	A. There was not.
7	Q. Were there slides or anything	7	Q. Now, do you have some role with
8	to accompany this oral presentation?	8	training people, residents?
9	A. I'm sure there were.	9	A. Yes, I do.
10	Q. Okay. Do you have those?	10	O. Where is that done?
11	A. No.	11	A. That's at Mercy.
12	Q. When did you decide that TVT®	12	Q. How many do you train per year
13	was so unsafe and never should have been	13	or however it works?
14	sold?	14	A. The program is accredited for
15	A. Few years after it came out.	15	six residents at each level for four years,
16	Q. Okay. So 2005 or before?	16	total of 24.
17	A. Around that time.	17	Q. So at any one time you're
18	Q. So what about these invited	18	dealing with 24?
19	here's an invited lecture, Perils for removal	19	A. There's 24 residents there.
20	of mesh, roundtable discussion, did you	20	It's one-on-one mostly when I'm dealing with
21	attend that?	21	them.
22	A. That, I did.	22	Q. But do you deal with all 24 of
23	Q. Are there any materials from	23	them throughout the course of the year?
24	that?	24	A. Yeah.
	that.		11. I cuii.
	Page 135		Page 137
1	A. No, that was simply a	1	Page 137 Q. That's what I meant. I didn't
1 2		1 2	Q. That's what I meant. I didn't mean you get all 24 together at once.
	A. No, that was simply a roundtable discussion.Q. And at that roundtable		Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the
2	A. No, that was simply a roundtable discussion.Q. And at that roundtable discussion, did you say either Gynemesh® PS	2	Q. That's what I meant. I didn't mean you get all 24 together at once.
2 3 4 5	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have	2 3 4 5	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes.
2 3 4	A. No, that was simply a roundtable discussion.Q. And at that roundtable discussion, did you say either Gynemesh® PS	2 3 4 5 6	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it?
2 3 4 5	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have	2 3 4 5	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No.
2 3 4 5 6 7 8	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was	2 3 4 5 6 7 8	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them
2 3 4 5 6 7 8	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that	2 3 4 5 6 7 8	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS?
2 3 4 5 6 7 8 9	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications.	2 3 4 5 6 7 8 9	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes.
2 3 4 5 6 7 8 9 10 11	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the	2 3 4 5 6 7 8 9 10 11	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that?
2 3 4 5 6 7 8 9 10 11 12	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston?	2 3 4 5 6 7 8 9 10 11 12	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time.
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2 3 4 5 6 7 8 9 10 11 12 13 14	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston? A. Yes. Q. So you have had occasions where	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a
2 3 4 5 6 7 8 9 10 11 12 13 14	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston? A. Yes. Q. So you have had occasions where you've made presentations about mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a sense of what they should do and shouldn't
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston? A. Yes. Q. So you have had occasions where you've made presentations about mesh complications to doctors, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a sense of what they should do and shouldn't do.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston? A. Yes. Q. So you have had occasions where you've made presentations about mesh complications to doctors, right? A. Yeah, it wasn't yes, I didn't consider that a presentation. I consider a presentation I get up at a podium and I give a talk. It was mostly at breakfast. Usually it's seven, eight people, two, three show up and, "How do you do this, how do you do that."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a sense of what they should do and shouldn't do. Q. There's a book chapter on here, Chapter 18, Dekker, Inc., published in 2003. Has that been updated since that ever? A. It's not been updated. Q. Okay. So it doesn't sound like you have; do you have anything in writing
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No, that was simply a roundtable discussion. Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold? A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications. Q. The same thing with the April 2013 roundtable in Charleston? A. Yes. Q. So you have had occasions where you've made presentations about mesh complications to doctors, right? A. Yeah, it wasn't yes, I didn't consider that a presentation. I consider a presentation I get up at a podium and I give a talk. It was mostly at breakfast. Usually it's seven, eight people, two, three show up and, "How do you do this,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. That's what I meant. I didn't mean you get all 24 together at once. Have you ever told the residents they should never use TVT®? A. Yes. Q. Okay. Never use it? A. No. Q. And have you ever told them they shouldn't use Gynemesh® PS? A. Yes. Q. When did you start doing that? A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a sense of what they should do and shouldn't do. Q. There's a book chapter on here, Chapter 18, Dekker, Inc., published in 2003. Has that been updated since that ever? A. It's not been updated. Q. Okay. So it doesn't sound like

	Page 138		Page 140
1	A. No.	1	A. It has the same issue with the
2	Q. Besides the residents, have you	2	round straw adaptation to the flat sling. I
3	told any other doctors that they that in	3	think it's pretty easy. We both learned in
4	your opinion they should not use TVT® slings?	4	second grade that you can't put a square peg
5	A. Yes.	5	in a round hole. So all of these trocars
6	Q. How many?	6	create a round opening and then they put a
7	A. The three or four that do	7	square piece in there and it immediately
8	slings at Mercy.	8	causes it to roll. It's a design flaw in
9	Q. Okay.	9	every manufacturer.
10	A. They ask me specifically what	10	So the only way to get around
11	products they should use, and I give them my	11	it is to have a sling that allows to you do
12	opinion.	12	surgery, open those spaces up, lay the sling
13	Q. Okay. Anybody else?	13	nice and flat, and the only product out
14	A. Anyone who has asked me.	14	there, and it doesn't fray, is Desara.
15	Q. Well, do they ask you what	15	Q. Does the Advantage sling have a
16	products you prefer, or do you affirmatively	16	fraying issue?
17	tell them, "Whatever you do, don't use TVT®"?	17	A. Yes.
18	A. No, I think we have a	18	
19	discussion. They ask, you know, "How should	19	Q. All right. So you're critical of the Boston Scientific Advantage product
20	I manage this, what product should I use,	20	U 1
21			both because it has an issue of fraying and
22	what approach should I use, how should I do	21 22	because it has an improper instrumentation?
	it, which products are available." And I		A. Yes.
23 24	tell them what's available anymore out there	23	Q. And does it also, in your view,
24	is not many more manufacturers left, and I	24	recommend inappropriate technique?
	Page 139		Page 141
1	recently had this discussion when AMS pulled	1	A. Yes.
2	their product and BARD pulled their product.	2	Q. So Advantage, Desara, TVT®, are
3	Some of the urology colleagues	3	there any other polypropylene sling products
4	and gynecology colleagues asked what they	4	on the market that you're aware of?
5	should do and what my opinion was. I didn't	5	A. Coloplast.
6	overly twist their arm to use it or not to	6	Q. Okay. And what's the name of
7	use it. I presented the pros and the cons of	7	theirs?
8	what I do, how I do it and why I do it and	8	A. The retropubic one is called
9	what's available out there, and I let them	9	Supris.
10	decide. Even though I feel strongly that	10	Q. Have you used it?
11	TVT® is not a good product, I didn't, you	11	A. I have not.
12	know, ram it down their throat and say,	12	Q. Does it have an instrumentation
13	"Don't use it."	13	problem?
14	Q. What is on the market today for	14	A. It has less of an
15	SUI mesh besides TVT® and Desara?	15	instrumentation problem.
16	A. Advantage Fit.	16	Q. Okay. Do you believe it has an
17	Q. And that's a Boston Scientific	17	unsafe instrument with it?
18	product?	18	A. Not as much because the
19	_	19	sling
		20	Q. I didn't ask as much. I'm not
20	Q. Do you believe that's a safe	21	there to ranking them yet. I'm just saying
21	product?	22	do you think it has a safe instrumentation or
22	A. No, it's not as good as Desara.	23	not?
23	Q. Okay. And what's unsafe about	24	A. No, it does not.
24	it?	4	A. NO, It does not.

36 (Pages 138 to 141)

	Page 142		Page 144
1	Q. It does not?	1	technique.
2	A. It does not.	2	Is the mesh itself safe with
3	Q. Okay. Does it have a safe	3	the Desara as far as you're concerned?
4	recommended technique?	4	A. The mesh has the same problem,
5	A. It has a recommend technique.	5	it is polypropylene and degrades.
6	Q. Is the recommended technique	6	Q. Do you consider it reasonably
7	safe?	7	safe, the mesh itself?
8	A. Not in my opinion.	8	A. Same category as all the
9	Q. Okay. And then the mesh	9	others.
10	itself, is the mesh itself safe?	10	Q. So is it fair to say that all
11	A. No.	11	of the meshes that are on the market today,
12	Q. Okay. So on the market today,	12	you consider all of them for SUI surgery to
13	is there anything else? That's the four.	13	be unsafe?
14	A. There's I-Stop. I don't see	14	A. At this point in time with
15	too much of that. Every now and then I get a	15	everything I've reviewed and everything I've
16	patient that has a problem. I don't know	16	learned, they are not safe.
17	who I don't know anyone that uses it	17	Q. Okay. None of them?
18	around here. These patients come from far	18	A. None of them.
19	away.	19	Q. Okay. And then in ranking,
20	Q. So the four that are used with	20	okay, we'll doing ranking now.
21	some regularity in the United States are	21	I assume because you use the
22	the what did you say the Coloplast was	22	Desara you believe it is the least unsafe?
23	called?	23	A. Yes.
24	A. Supris.	24	Q. Okay. What's next? If it
	Page 143		Page 145
1	Q. The Supris, the Advantage, the	1	wasn't around, what would you use next?
2	TVT® and the Desara?	2	A. I probably wouldn't use any. I
3	A. Yes.	3	would probably go to cadaver or do something
4	Q. Okay. And all of those, as far	4	else.
5	as you're concerned, have unsafe	5	Q. So the other three, the
6	instrumentation?	6	Coloplast, the Boston Scientific and the
7	A. Yes.	7	TVT®, those SUI sling products, you just
8	Q. And all of them have an unsafe	8	wouldn't use them, period, true?
_	1 1 . 1 . 2	۱ ۵	
9	recommended technique?	9	A. Definitely not.
10	A. Yes.	10	A. Definitely not.Q. True?
	A. Yes.Q. And all of them, except the		•
10	A. Yes.	10	Q. True?
10 11	A. Yes.Q. And all of them, except the	10 11	Q. True? A. Yes.
10 11 12	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara	10 11 12	Q. True?A. Yes.Q. Are there any studies showing
10 11 12 13	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes.	10 11 12 13	Q. True?A. Yes.Q. Are there any studies showing the long-term efficacy and complication of
10 11 12 13 14	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara	10 11 12 13 14	Q. True?A. Yes.Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling?
10 11 12 13 14 15	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not?	10 11 12 13 14 15	 Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No.
10 11 12 13 14 15	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the	10 11 12 13 14 15	 Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still
10 11 12 13 14 15 16 17	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the difference between the Supris and the pore	10 11 12 13 14 15 16 17	 Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still on the market, would you use it?
10 11 12 13 14 15 16 17	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the difference between the Supris and the pore size and the configuration and the diameter,	10 11 12 13 14 15 16 17	Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still on the market, would you use it? A. Yes. That would be my
10 11 12 13 14 15 16 17 18	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the difference between the Supris and the pore size and the configuration and the diameter, comparing that to the TVT® and then comparing	10 11 12 13 14 15 16 17 18 19	 Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still on the market, would you use it? A. Yes. That would be my preferred sling.
10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the difference between the Supris and the pore size and the configuration and the diameter, comparing that to the TVT® and then comparing all of it to each other real quick.	10 11 12 13 14 15 16 17 18 19 20	Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still on the market, would you use it? A. Yes. That would be my preferred sling. Q. Above the Desara?
10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. And all of them, except the Desara, have an unsafe mesh? A. Yes. Q. Okay. And maybe is the Desara a safe mesh or not? A. Yeah, I was thinking of the difference between the Supris and the pore size and the configuration and the diameter, comparing that to the TVT® and then comparing all of it to each other real quick. Q. So does Desara have a safe or	10 11 12 13 14 15 16 17 18 19 20 21	Q. True? A. Yes. Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling? A. No. Q. If the Uretex sling were still on the market, would you use it? A. Yes. That would be my preferred sling. Q. Above the Desara? A. Yes.

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	Page 146		Page 148
1	and I think Covidien purchased them. BARD	1	Uretex warnings and the TVT® warnings, were
2	didn't purchase them, so they lost the rights	2	they different in any way that was
3	to import the sling.	3	significant to you during that time period?
4	Q. So is that sling still on the	4	A. They were the same, but I want
5	market somewhere?	5	to qualify that I didn't read or look at the
6	A. I don't think so.	6	Caldera Desara until 2010. So I already knew
7	Q. In your opinion about the	7	what the IFU was for the Uretex and the TVT®.
8	relative merits of the various slings and	8	Q. But you looked when you
9	instruments and techniques, you're not aware	9	looked at it in 2010, did you notice it being
10	of any medical review or medical literature	10	significantly different in terms of
11	that makes a comparison like that and reaches	11	warnings
12	those kinds of conclusions, true?	12	A. It had a lot the Desara had
13	A. True.	13	a lot more warnings.
14	Q. Okay. This is all essentially	14	Q. Okay. In January 2010?
15	based on your personal opinion based on your	15	A. Yes.
16	personal experience?	16	Q. Do you know when it came on the
17	A. Yes.	17	market?
18	Q. Let's take 2005 to 2010.	18	A. Around that time.
19	During that time period, were the IFU	19	Q. Okay.
20	warnings any different for the Uretex or the	20	A. I was looking for another
21	Desara sling versus the TVT® in any material	21	sling, they were at a conference and I asked
22	way?	22	to be evaluated.
23	A. 2005?	23	Q. So the Uretex and TVT® slings
24	Q. To 2010, during that time	24	had substantially the same warnings, right,
	Page 147		Page 149
1	period?	1 1	
	•	1	during the time they were on the market in
2	A. So I was not using Desara.	2	2003 to 2010?
3	A. So I was not using Desara.Q. Well, I thought you said you	2	2003 to 2010? A. I think the Uretex had more
3 4	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it.	2 3 4	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the
3 4 5	 A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started 	2 3 4 5	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the TVT®.
3 4 5 6	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010.	2 3 4 5 6	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010
3 4 5	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and	2 3 4 5	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the TVT®.
3 4 5 6 7 8	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003?	2 3 4 5 6 7 8	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes.
3 4 5 6 7 8 9	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay.	2 3 4 5 6 7 8	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them?
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3 4 5 6 7 8 9 10	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex?	2 3 4 5 6 7 8 9 10	2003 to 2010? A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more
3 4 5 6 7 8 9 10 11 12	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex? A. Uh-huh.	2 3 4 5 6 7 8 9 10 11 12	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect
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3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex? A. Uh-huh. Q. During that time period, were the warnings in the IFU about the SUI slings any different in a material way between the Uretex IFU, the Desara IFU and the TVT® IFU? A. With respect to the material?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect from a sling. Q. There was more of that type of warning 2003 to 2010 with the Uretex product than the TVT®? A. Yes.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex? A. Uh-huh. Q. During that time period, were the warnings in the IFU about the SUI slings any different in a material way between the Uretex IFU, the Desara IFU and the TVT® IFU? A. With respect to the material? Q. No, with respect by material, I meant relevant or a significant way. Let me reask the question. I'll get	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect from a sling. Q. There was more of that type of warning 2003 to 2010 with the Uretex product than the TVT®? A. Yes. Q. Okay. And then the Desara was kind of a new generation sling as of January of 2010?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex? A. Uh-huh. Q. During that time period, were the warnings in the IFU about the SUI slings any different in a material way between the Uretex IFU, the Desara IFU and the TVT® IFU? A. With respect to the material? Q. No, with respect by material, I meant relevant or a significant way. Let me reask the question. I'll get rid of the word "material."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect from a sling. Q. There was more of that type of warning 2003 to 2010 with the Uretex product than the TVT®? A. Yes. Q. Okay. And then the Desara was kind of a new generation sling as of January of 2010? A. Yes.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. So I was not using Desara. Q. Well, I thought you said you started in 2010, that's why I included it. A. Okay. So from I started January 2010. Q. So starting January 2010 and going backward to 2003? A. Okay. Q. Which is when you started using the Uretex? A. Uh-huh. Q. During that time period, were the warnings in the IFU about the SUI slings any different in a material way between the Uretex IFU, the Desara IFU and the TVT® IFU? A. With respect to the material? Q. No, with respect by material, I meant relevant or a significant way. Let me reask the question. I'll get rid of the word "material." A. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I think the Uretex had more warnings than the warnings that were in the TVT®. Q. Okay. During the 2003 to 2010 time period? A. Yes. Q. And what was more about them? A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect from a sling. Q. There was more of that type of warning 2003 to 2010 with the Uretex product than the TVT®? A. Yes. Q. Okay. And then the Desara was kind of a new generation sling as of January of 2010? A. Yes. Q. And it had more warnings?

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	Page 150		Page 152
1	you because there had been many more years of	1	Ethicon to help educate doctors?
2	experience?	2	Did you review those?
3	A. Yes.	3	A. I reviewed what was available
4	Q. Now, in terms of warnings to	4	to me.
5	doctors, manufacturers can get warning	5	Q. Were there any different
6	information to doctors through methods other	6	warnings in the professional education
7	than the IFU, true?	7	materials for the TVT® or the Gynemesh® PS
8	A. Yes.	8	more than in the IFU?
9	Q. Professional education programs	9	A. No.
10	can provide warnings, right?	10	Q. But you don't make with
11	A. Yes.	11	respect to your warning sections in both the
12	Q. There can be surgeon monographs	12	Gynemesh® report and the TVT® report, the
13	that can supply warnings?	13	only warnings you refer to are warnings that
14	A. Yes.	14	are in the IFU, true?
15	Q. Have you evaluated any of the	15	A. Yes. And I based that on the
16	sources of warnings that Ethicon gave to	16	fact that that was a sure thing for me that
17	doctors other than the IFU?	17	that came with the kit.
18	A. Yes, I've looked at some	18	I don't know whether the
19	material.	19	surgeons viewed the video, looked at the
20	Q. In your report, do you make	20	pamphlets. I am not sure what they had done.
21	reference to any other materials that	21	But that was a constant.
22	contained warnings other than the IFU?	22	Q. But in any particular case, you
23	A. No. Because essentially	23	would want to examine all of the information
24	information was the same as the IFU, and I	24	that was available from Ethicon to the
	Page 151		Page 153
1	relied on the sure bet that that information	1	doctors in order to assess the adequacy of
2	relied on the sure bet that that information was always with the product rather than	2	doctors in order to assess the adequacy of the warnings, true?
2	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B	2 3	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the
2 3 4	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material.	2 3 4	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the IFU. I think it's the same.
2 3 4 5	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material. Q. Have you ever reviewed the	2 3	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the IFU. I think it's the same. Q. Your belief is that none of the
2 3 4	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material. Q. Have you ever reviewed the surgeon monograph with respect to the	2 3 4	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the IFU. I think it's the same. Q. Your belief is that none of the materials had any different warnings in them?
2 3 4 5	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material. Q. Have you ever reviewed the	2 3 4 5	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the IFU. I think it's the same. Q. Your belief is that none of the materials had any different warnings in them? A. Correct.
2 3 4 5 6 7 8	relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material. Q. Have you ever reviewed the surgeon monograph with respect to the Prolift® product, which was a Gynemesh® PS product?	2 3 4 5 6 7 8	doctors in order to assess the adequacy of the warnings, true? A. Not if they're the same as the IFU. I think it's the same. Q. Your belief is that none of the materials had any different warnings in them? A. Correct. Q. Okay. Are there any warnings
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39 (Pages 150 to 153)

	Page 154		Page 156
1	A. With everything yes, with	1	broad question first.
2	everything I know today, they are not	2	A. Yes.
3	adequate.	3	Q. Do you have an opinion as to
4	Q. None of them?	4	the frequency of any of the potential
5	A. None of them.	5	complications with a TVT®?
6	Q. And you're saying this because	6	A. Two-part answer.
7	they don't state frequency?	7	Q. Okay.
8	A. Yes.	8	A. No, because I don't know the
9	Q. Okay. Frequency of what?	9	denominator.
10	A. How often is there a bladder	10	Q. Right.
11	perforation, how often is there an exposure,	11	A. And I don't know what I know
12	how much mesh contracture occurs, what are	12	for certain are the patients that present to
13	the pore sizes, what happened to the	13	me with those complications, and the patients
14	effective pore size. It's a very small	14	that present to other surrounding surgeons
15	percentage of the information that any doc	15	with those complications. So the only way to
16	needs to truly understand what he or she is	16	know that is to pool a very large number of
17	going to offer that patient and how to	17	docs and figure out what it is. And even if
18	counsel that patient.	18	you found out what it was, you would have to
19	So everything we tell a patient	19	know the exact number of slings that went in.
20	before surgery is based on what our	20	Q. So do you believe that the
21	understanding is and our best efforts at	21	percentages of any of the complications with
22	explaining those risks and benefits to the	22	the TVT® such as exposure, chronic foreign
23	patients. So when it's very small, you don't	23	body reaction, chronic pain with intercourse,
24	have enough information to truly counsel a	24	do you believe that is knowable?
21	have chough information to truly counsel a	24	do you believe that is knowable:
	Page 155		
	Page 155		Page 157
1	patient effectively.	1	Page 157 A. It can be knowable, yes.
1 2		1 2	
	patient effectively.		A. It can be knowable, yes.
2	patient effectively. Q. Today is your counseling of the	2	A. It can be knowable, yes. Q. Okay. So do you know of anyone or any paper or anything that would give reliable percentages of the frequency of
2 3	patient effectively. Q. Today is your counseling of the patient based more on the IFU or on your own personal experience? A. Both.	2	A. It can be knowable, yes. Q. Okay. So do you know of anyone or any paper or anything that would give reliable percentages of the frequency of complications such as dyspareunia,
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	Page 158		Page 160
1	Q. I mean, the general, if they	1	A. True.
2	ask you just generally, not just you, Doc,	2	Q. You said that you gave the
3	just generally	3	general numbers like 85 percent cure and 7 or
4	A. 25 percent. 25 percent.	4	8 percent improvement with mesh slings.
5	Q have dyspareunia?	5	Remember that?
6	A. 25 percent can have	6	A. That was with the TVT®.
7	dyspareunia.	7	Q. TVT®.
8	Q. Okay. What's your source for	8	Are there any general numbers
9	that number?	9	like that for other products?
10	A. That source is a paper by	10	A. Yes.
11	Hilary Cholhan.	11	Q. What are they?
12	Q. And that's not is that	12	A. I know the Mersilene sling by
13	long-term dyspareunia or temporary or both?	13	Steve Young had a 94 percent success rate.
14	A. It was de novo dyspareunia.	14	Q. Okay.
15	Q. But long term or	15	A. Studies cite fascial slings
16	A. It never got followed up,	16	95 percent.
17	reported after that.	17	Q. I was talking about polyester
18	Q. That's all products, not just	18	slings.
19	TVT®?	19	Are there any results on the
20	A. That was not just specific	20	Desara sling, the Uretex and the other ones
21	TVT®.	21	that you've mentioned?
22	Q. Is that what you tell patients	22	MR. MATTHEWS: Object to the
23	then, that there's a 25 percent chance of	23	form. Those are not polyester slings.
24	dyspareunia with a general percentage with	24	MR. BALL: Polypropylene. That
			71 17
	Page 159		D 161
	1436 137		Page 161
1	mesh?	1	was my error.
2	mesh? A. No. Because I don't follow the	1 2	was my error. MR. MATTHEWS: Okay.
	mesh? A. No. Because I don't follow the manufacturer's instructions for placement.		was my error. MR. MATTHEWS: Okay. QUESTIONS BY MR. BALL:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	M. No. Because I don't follow the manufacturer's instructions for placement. Q. What if they ask you what the general percentages of exposure or erosion, do you give a percentage? A. It's from 4 to 12. 4, 18, 17 percent. It depends on Q. I'm getting confused because a minute ago I asked you if there were any published studies about these percentages, and you said no, and now you're rattling off. I'm having trouble. A. There are some papers that talk about, but they're very small groups and the percentages are all over the board. Q. So I think I used the word "reliable," and I think that's so you're not aware of any reliable scientific papers that have been published that give what you think are reliable estimates of the percentage of complications of dyspareunia,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	was my error. MR. MATTHEWS: Okay. QUESTIONS BY MR. BALL: Q. Polypropylene slings, the other ones, is there any data that you find reliable about the success rates with other polypropylene slings? A. There's data to suggest that all slings have a high cure rate. Q. Of? A. 85, 90. Depending whether you look at objective or subjective data, sometimes that a little bit different. Q. So in terms of success rates, the TVT® sling is consistent with the other polypropylene slings that have been on the market the last 10 or 15 years, true? A. Yes. Q. Okay. And in terms of complications, you don't have reliable data to compare the rate of complications with TVT® versus the other polypropylene slings
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. No. Because I don't follow the manufacturer's instructions for placement. Q. What if they ask you what the general percentages of exposure or erosion, do you give a percentage? A. It's from 4 to 12. 4, 18, 17 percent. It depends on Q. I'm getting confused because a minute ago I asked you if there were any published studies about these percentages, and you said no, and now you're rattling off. I'm having trouble. A. There are some papers that talk about, but they're very small groups and the percentages are all over the board. Q. So I think I used the word "reliable," and I think that's so you're not aware of any reliable scientific papers that have been published that give what you think are reliable estimates of the percentage of complications of dyspareunia, pelvic pain, erosion, contraction, that type	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	was my error. MR. MATTHEWS: Okay. QUESTIONS BY MR. BALL: Q. Polypropylene slings, the other ones, is there any data that you find reliable about the success rates with other polypropylene slings? A. There's data to suggest that all slings have a high cure rate. Q. Of? A. 85, 90. Depending whether you look at objective or subjective data, sometimes that a little bit different. Q. So in terms of success rates, the TVT® sling is consistent with the other polypropylene slings that have been on the market the last 10 or 15 years, true? A. Yes. Q. Okay. And in terms of complications, you don't have reliable data to compare the rate of complications with TVT® versus the other polypropylene slings that have been on the market the last 10 or
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41 (Pages 158 to 161)

	Page 162		Page 164
1	A. True.	1	instrument to do pelvic surgery, sacrospinous
2	Q. I wanted to ask you before we	2	colpopexy.
3	get into the Prolift® here, can you tell	3	Q. Have those been commercialized,
4	me	4	those products?
5	MR. BALL: Let's go off the	5	A. Yes.
6	record for a second.	6	Q. And did you write the warnings
7	(Off the record at 11:52 a.m.)	7	in the IFU?
8	QUESTIONS BY MR. BALL:	8	A. Yes.
9	Q. Are you aware of any published	9	Q. Or just the technique?
10	scientific literature that is critical of the	10	A. I wrote both.
11	instruments used with TVT®?	11	Q. Okay. Did anyone help you
12	A. No.	12	write the warnings?
13	Q. Are you aware of any published	13	A. They gave me a handout on what
14	scientific papers that are critical with the	14	it should include, and I wrote it.
15	technique recommended in the IFU for the	15	Q. If I wanted to have those IFUs,
16	TVT®?	16	where would I get them?
17	A. No.	17	A. I don't know where you would
18	Q. Are you aware of any scientific	18	get them at this time. Here's why: The
19	papers that are critical of the mesh design	19	company got sold. Currently the product got
20	with the TVT®?	20	bought by let me think. I'll think of it
21	A. No.	21	in a second. I'll think of it.
22	Q. Okay. Have you read do you	22	So I did not have a binding
23	know which versions of the IFU well, let	23	contract with the company that I did this for
24	me back up.	24	so when they sold it to oh, I'll think of
	-		•
	Page 163		Page 165
1	Have you read the IFU that	1	the name. Who are they?
2	accompanies TVT® today?	2	So I don't get any royalties or
3	A. I don't think so.	3	anything on that. I don't know where it's
4	Q. Okay. So you don't have any	4	at.
5	opinion as to whether it's adequate or not,		
		5	Q. Do you have copies of the IFUs
6	the warnings in there?	5 6	Q. Do you have copies of the IFUs for those products?
6 7	the warnings in there? A. No, I actually tried to click		
7 8	the warnings in there? A. No, I actually tried to click on it several times and it didn't download	6 7 8	for those products?
7 8 9	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version.	6 7 8 9	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not.
7 8 9 10	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who	6 7 8	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of
7 8 9 10 11	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other	6 7 8 9 10 11	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in
7 8 9 10 11 12	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings?	6 7 8 9 10	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing?
7 8 9 10 11 12 13	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the	6 7 8 9 10 11	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct.
7 8 9 10 11 12 13 14	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question.	6 7 8 9 10 11 12 13 14	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU,
7 8 9 10 11 12 13 14 15	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to	6 7 8 9 10 11 12 13 14 15	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other
7 8 9 10 11 12 13 14 15	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the	6 7 8 9 10 11 12 13 14 15 16	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors
7 8 9 10 11 12 13 14 15 16	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs?	6 7 8 9 10 11 12 13 14 15 16 17	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a
7 8 9 10 11 12 13 14 15 16 17	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several	6 7 8 9 10 11 12 13 14 15 16 17	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing
7 8 9 10 11 12 13 14 15 16 17 18	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've	6 7 8 9 10 11 12 13 14 15 16 17 18	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they
7 8 9 10 11 12 13 14 15 16 17 18 19 20	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've designed.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've designed. Q. For what?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true? A. Sure, yes.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've designed. Q. For what? A. One was for a vaginal dilator	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true? A. Sure, yes. Q. And they also have a
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've designed. Q. For what? A. One was for a vaginal dilator for women that have a shortened vagina.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true? A. Sure, yes. Q. And they also have a responsibility to be aware, for example, of
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the warnings in there? A. No, I actually tried to click on it several times and it didn't download for me to get the latest version. Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings? A. I'm not sure I understand the question. Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs? A. I've written several instructions for use on instruments I've designed. Q. For what? A. One was for a vaginal dilator	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	for those products? A. I'm sure I don't. Q. Do you still use the products? A. I do not. Q. So you don't have any copies of IFUs that you've ever been involved in writing? A. That's correct. Q. In addition to the IFU, doctors in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true? A. Sure, yes. Q. And they also have a

42 (Pages 162 to 165)

	Page 166		Page 168
1	use, true?	1	where she was encouraging you to try TVT®,
2	A. Yes.	2	and you tried it, and you told her what your
3	Q. And also the position	3	issues were, right?
4	statements and publications of the	4	A. Yes.
5	organizations they're members of, true?	5	Q. Anything else about those
6	A. Yes.	6	communications that you can recall?
7	Q. And those can all be sources of	7	A. No. Nice lady. She wanted me
8	information about warnings, true?	8	to try it, and I declined.
9	A. Yes.	9	Q. Well, you tried it and then
10	Q. Are there more cites in your	10	declined using it more?
11	reports to company documents or peer-reviewed	11	A. Right. Yes.
12	literature?	12	Q. By the way, did the two people
13	A. Probably company documents.	13	you tried it on have any long-term problems,
14	Q. Why is that?	14	do you know?
15	A. I thought that that was a very	15	A. No, I don't think so.
16	relevant source of things that were not in	16	Q. And then you also mentioned a
17	the peer-reviewed literature that truly spoke	17	Will Irby at one point in time that you had a
18	to the issues that the mesh had that were not	18	conversation with.
19	evident by any peer-reviewed literature.	19	A. Yes.
20	Q. One reason I want to cover	20	Q. Who was he?
21	before we get into the Gynemesh® is I want to	21	A. I don't recall his exact title,
22	make sure that I understand and have on the	22	but he had something to do with maybe the
23	record any communications that you recall	23	product manager for TVT®.
24	having with anybody who worked for Ethicon.	24	Q. Okay. And what were the nature
	Page 167		Page 169
1	Okay?	1	of your communications with him?
2	A. Okay.	2	A. He was introduced to me by
3	Q. All right. So, first of all, I	3	Hattie Loggie as someone who might be a
4	think you said back in the early 2000s there	4	potential customer for using TVT®.
5			
J	was a person who encouraging you to try TVT®,	5	Q. Okay. And what was the
6	was a person who encouraging you to try TVT®, right, and you gave us a name earlier in the	5 6	
			Q. Okay. And what was the nature and then just tell me about those communications.
6	right, and you gave us a name earlier in the	6	Q. Okay. And what was the nature and then just tell me about those
6 7	right, and you gave us a name earlier in the deposition, and it escapes me?	6 7	Q. Okay. And what was the nature and then just tell me about those communications.
6 7 8	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie.	6 7 8	Q. Okay. And what was the nature and then just tell me about those communications.A. My recollection is I met the
6 7 8 9	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her	6 7 8 9	Q. Okay. And what was the nature and then just tell me about those communications.A. My recollection is I met the man once. It was in my office. I asked
6 7 8 9	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI	6 7 8 9 10	 Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the
6 7 8 9 10 11	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some	6 7 8 9 10 11	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time
6 7 8 9 10 11	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember	6 7 8 9 10 11 12	 Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you
6 7 8 9 10 11 12	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications?	6 7 8 9 10 11 12 13	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with
6 7 8 9 10 11 12 13	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her?	6 7 8 9 10 11 12 13	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before.
6 7 8 9 10 11 12 13 14	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes.	6 7 8 9 10 11 12 13 14 15	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before?
6 7 8 9 10 11 12 13 14 15	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I	6 7 8 9 10 11 12 13 14 15	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before.
6 7 8 9 10 11 12 13 14 15 16	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I had communications with her.	6 7 8 9 10 11 12 13 14 15 16	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before. Q. So this was kind of in
6 7 8 9 10 11 12 13 14 15 16 17	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I had communications with her. Q. I'm going to get to other	6 7 8 9 10 11 12 13 14 15 16 17	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before. Q. So this was kind of in conjunction with you trying it out the first
6 7 8 9 10 11 12 13 14 15 16 17 18	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I had communications with her. Q. I'm going to get to other people in a minute. I want to take them one	6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before. Q. So this was kind of in conjunction with you trying it out the first time?
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I had communications with her. Q. I'm going to get to other people in a minute. I want to take them one at a time.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before. Q. So this was kind of in conjunction with you trying it out the first time? A. Yeah. Yes. Q. Okay. Anybody else from
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	right, and you gave us a name earlier in the deposition, and it escapes me? A. Hattie Loggie. Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications? A. With her? Q. Yes. A. No, I remember there was I had communications with her. Q. I'm going to get to other people in a minute. I want to take them one at a time. A. I am sorry, ask that question	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay. And what was the nature and then just tell me about those communications. A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time Q. Was this before or after you tried it with A. It was before. Q. Before? A. Yeah, it was before. Q. So this was kind of in conjunction with you trying it out the first time? A. Yeah. Yes.

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	Page 170		Page 172
1	Q. Yes.	1	Gynemesh®.
2	A. Now, there was a Jim Bly, but I	2	A. Okay.
3	think that was regarding TVT-Secur. So I	3	Q. Prolapse products.
4	think retropubic TVT® was Will Irby. There	4	A. Okay.
5	was Hattie Loggie. There was maybe her	5	MR. MATTHEWS: Well, he didn't
6	regional manager, Hattie's regional manager,	6	give an opinion on Prolift®.
7	that moved to Atlanta, but I can't recall his	7	MR. BALL: He gave an opinion
8	name.	8	about Gynemesh®.
9	Q. And that was all about wanting	9	MR. MATTHEWS: Right. That's
10	you to try it out, and you tried it out, and	10	two different things.
11	you told them your thoughts?	11	MR. BALL: Yeah, I understand.
12	A. Yes.	12	But his report is full of references
13	And after I tried it, I think	13	to Prolift®. Okay.
14	Hattie set up this meeting. I remember	14	QUESTIONS BY MR. BALL:
15	they we went to dinner at Morton's and he	15	Q. Is Prolift® made out of
16	asked me what my concerns were, and I relayed		Gynemesh® PS?
17	•	16 17	A. It is.
	then my concerns about the tunneling, the		
18	curling, the rolling, the fraying, all of	18	Q. All right. And did you ever
19 20	those things.	19	have any communications with anybody from
	Q. Now, did you get any specific	20	Ethicon connected with any product made out
21	training on using the TVT® before you tried	21	of Gynemesh® PS?
22	it out?	22	A. So let me just think out loud
23	A. Yes.	23	for a second.
24	Q. What was the nature of that	24	Okay?
	Page 171		D 102
	1490 171		Page 173
1	training?	1	There was a young lady that
1 2		1 2	
	training?		There was a young lady that
2	training? A. I think there was some sort of course. I remember being flown. I don't	2	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a
2 3	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was	2 3	There was a young lady that drove me to Wichita, Kansas, to watch Dave
2 3 4	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty	2 3 4	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for
2 3 4 5	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred	2 3 4 5	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So
2 3 4 5 6	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty	2 3 4 5 6	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his
2 3 4 5 6 7	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and	2 3 4 5 6 7	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's
2 3 4 5 6 7 8	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and	2 3 4 5 6 7 8	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me
2 3 4 5 6 7 8 9	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®?	2 3 4 5 6 7 8	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I
2 3 4 5 6 7 8 9	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes.	2 3 4 5 6 7 8 9	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson.
2 3 4 5 6 7 8 9 10	A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried	2 3 4 5 6 7 8 9 10	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery?
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2 3 4 5 6 7 8 9 10 11 12 13 14	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here	2 3 4 5 6 7 8 9 10 11 12 13 14	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that? A. No. Q. Did you ever go over to France	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used Gynemesh® PS any? A. I had not.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that? A. No. Q. Did you ever go over to France with Prolift®? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used Gynemesh® PS any? A. I had not. Q. Okay. Any other communications
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that? A. No. Q. Did you ever go over to France with Prolift®?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used Gynemesh® PS any? A. I had not. Q. Okay. Any other communications you had with anybody from Ethicon about any
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that? A. No. Q. Did you ever go over to France with Prolift®? A. No. Q. Or Gynemesh®? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used Gynemesh® PS any? A. I had not. Q. Okay. Any other communications you had with anybody from Ethicon about any Gynemesh® PS product?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	training? A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and Q. This is about TVT®? A. Yes. Q. And this was before you tried it the first time? A. Yes. Q. Did you ever go locally here and watch anybody or have any training from that? A. No. Q. Did you ever go over to France with Prolift®? A. No. Q. Or Gynemesh®?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson. Q. Dr. Robinson did the surgery? A. Yes. Q. Okay. And you watched him do it? A. I watched him do it. Q. Okay. That's one episode. At that time had you used Gynemesh® PS any? A. I had not. Q. Okay. Any other communications you had with anybody from Ethicon about any

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	Page 174		Page 176
1	Q. What happened at the end of	1	squared. It has
2	that Wichita trip?	2	Q. So it's lighter?
3	A. Like typically what happens,	3	A. It's lighter, which is why TVT®
4	they want you to become a customer, try the	4	is considered heavy. And learning all of
5	product. It seemed like Dr. Robinson put it	5	this and thinking about it, reading about it
6	in pretty smooth. It seemed smooth. He	6	and everybody's in a lightweight mesh, you
7	talked about what the advantages,	7	think that someone would make a sling that's
8	disadvantages were. I was very comfortable	8	lightweight. The pores have a funny
9	doing vaginal surgery, doing sacrospinous.	9	configuration. They're not the same. They
10	And my interactions with Dave, a couple years	10	vary in size, and there's a fiber that runs
11	before he was interested in that instrument	11	across it. So depending on how you measure
12	that I developed for doing sacrospinous and	12	it, you can get something from very small to
13	accessing that area of the pelvic floor and	13	1 millimeter to 1.5 to .3. It's all over.
14	that really don't think I have any other	14	Q. Are the TVT® pore sizes that
15	recollection besides that.	15	consistent?
16	Anybody else? I think Jim Bly,	16	A. Before you implant it, yes.
17	maybe Jim Bly brought me. I always like to	17	Q. So far the differences between
18	have stuff. I always like to play with it,	18	TVT® and Gynemesh® PS is irregularity in pore
19	touch it, read things, look at the trocars.	19	
20	I'm very hands-on, mechanical.	20	size and also the weight.
21	•	21	Anything else?
22	Q. What's Jim Bly's role?A. He's a salesperson.	22	A. They're both polypropylene.
23	÷		Q. Is the polypropylene the same,
24	Q. But you think that was about the TVT-O or about the	23	to your knowledge?
24	the 1 v 1-O or about the	24	A. Yes.
	Page 175		Page 177
1	A. No.	1	Q. Okay.
2	Q or the Secur?	2	A. They're both polypropylene.
3	A. He was about Prolift® and	3	The TVT®'s used for slings. The Gynemesh® is
4	Secur.	4	used for prolapse, cystocele, rectocele,
5	Q. Okay. And you think you did	5	vaginal apex support. Variable size in the
6	have some interaction with him about a	6	pores. Color's different. It's got blue
7	Gynemesh® PS product Prolift®?	7	stripes in the Gynemesh® where the early TVT®
8	A. It was about a posterior	8	was clear. Later TVT® is blue.
9	Prolift®. I still have it.	9	Q. Is Gynemesh® PS a lightweight,
10	No. No, it was a total	10	macroporous, monofilament mesh?
11	Prolift®. It was a total.	11	A. It's medium weight,
12	Q. And what was that communication	12	macroporous, monofilament.
13	about?	13	Q. What's the dividing line
14	A. Basically wanting me to try it.	14	between light and medium
15	Q. Okay. So any other	15	A. About 28, 28 I am sorry.
16	communications?	16	Q. We've been doing great.
17	A. Jogging my memory, that's all I	17	A. Sorry.
18	remember.	18	Q. Lightweight cutoff is what?
19	Q. Okay. Do you know if there's	19	What were you just going to say?
20	any difference between the mesh that is	20	A. 28 to 30 grams per meter
21	Gynemesh® PS and the mesh used in TVT®?	21	squared.
22	A. Yes, there is.	22	Q. And below, that's lightweight?
44		l	
	O. What's the difference?	23	A. Yes.
22 23 24	Q. What's the difference?A. Well, PS is 45 grams per meter	23 24	A. Yes.Q. And 30 to what is medium

45 (Pages 174 to 177)

	Page 178		Page 180
1	weight?	1	Q. All right. Just remembered.
2	A. 60, 50.	2	When you do an implant of a TVT® or excuse
3	Q. And above 50 or 60 is	3	me, an explant of a TVT®, the surgeries that
4	heavyweight in your view?	4	come to you, what has been your success rate
5	A. Yes.	5	in resolving their problems?
6	Q. I'm now going to be asking you	6	A. A percentage, you're looking
7	principally about Gynemesh® PS, okay, so	7	for a percentage?
8	we're switching gears. It doesn't mean that	8	Q. Yes.
9	there might not be some overlap, but we're	9	A. 95 percent.
10	switching gears.	10	Q. Okay. And when you do that, do
11	Doctor, can you tell me	11	you do something else to deal with their
12	first of all, have you ever used Gynemesh®	12	stress urinary incontinence?
13	PS?	13	A. Not at that time.
14	A. Yes.	14	Q. Okay. You take out the sling
15	Q. Okay. Kind of globally tell me	15	and kind of see how they do, is that the
16	what your experience is using that, and then	16	idea?
17	I'll ask you more specific questions.	17	A. Yes.
18	A. I didn't like it.	18	Q. And sometimes you have to,
19	Q. Well, I didn't ask whether you	19	what, put in another sling or do some other
20	liked it or not yet. I kind of figured you	20	kind of procedure?
21	didn't like it or you wouldn't be here.	21	A. Yes.
22	What have you used Gynemesh® PS	22	Q. What percentage of the time
23	for?	23	that you've taken out a TVT® do you have to
24	A. I've never used Gynemesh® PS.	24	do some other kind of procedure?
	A. The never used Gynemesn@15.	24	do some other kind of procedure?
	Page 179		- 101
	rage 177		Page 181
1	I've used Prolift®, which has Gynemesh® PS.	1	A. It's a great question. About
1 2		1 2	
	I've used Prolift®, which has Gynemesh® PS.		A. It's a great question. About
2	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so	2	A. It's a great question. About half the time.
2 3	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up.	2 3	A. It's a great question. About half the time.Q. About half the time.
2 3 4	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is	2 3 4	 A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking
2 3 4 5	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right?	2 3 4 5	A. It's a great question. About half the time.Q. About half the time.And then the other half, you take it out and they're okay?
2 3 4 5 6	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes.	2 3 4 5 6	 A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking
2 3 4 5 6 7	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh®	2 3 4 5 6 7	 A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from
2 3 4 5 6 7 8	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have	2 3 4 5 6 7 8	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they
2 3 4 5 6 7 8	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes.	2 3 4 5 6 7 8 9	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all.
2 3 4 5 6 7 8 9	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have	2 3 4 5 6 7 8 9	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half
2 3 4 5 6 7 8 9 10	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®?	2 3 4 5 6 7 8 9 10	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all.
2 3 4 5 6 7 8 9 10 11 12	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do?
2 3 4 5 6 7 8 9 10 11 12 13	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that?	2 3 4 5 6 7 8 9 10 11 12 13	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I
2 3 4 5 6 7 8 9 10 11 12 13 14	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave	2 3 4 5 6 7 8 9 10 11 12 13 14	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new patient, so to speak?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have complications?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have complications? A. Yes. Q. Okay. In what nature?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new patient, so to speak? A. And they are sort of a new patient because I don't do partial removals. I do complete removals so the entire pelvis
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have complications? A. Yes. Q. Okay. In what nature? A. She had protracted pain.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new patient, so to speak? A. And they are sort of a new patient because I don't do partial removals. I do complete removals so the entire pelvis is sort of naïve except with scarring from
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have complications? A. Yes. Q. Okay. In what nature? A. She had protracted pain. Q. Did it eventually go away?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new patient, so to speak? A. And they are sort of a new patient because I don't do partial removals. I do complete removals so the entire pelvis is sort of naïve except with scarring from multiple surgeries. But it gets her back to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I've used Prolift®, which has Gynemesh® PS. Q. But I'm encompassing so what what have you used let me back up. Gynemesh® PS Prolift® is made out of Gynemesh® PS, right? A. Yes. Q. All right. The only Gynemesh® PS you've used is Prolift®? A. Yes. Q. Okay. And how many times have you used Prolift®? A. Just once. Q. Okay. And when was that? A. Shortly after I visited Dave Robinson. Q. Okay. Did that patient have complications? A. Yes. Q. Okay. In what nature? A. She had protracted pain. Q. Did it eventually go away? A. She didn't come back.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It's a great question. About half the time. Q. About half the time. And then the other half, you take it out and they're okay? A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all. Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do? A. I offer them everything as I mentioned above. Because Q. Just as if they're a new patient, so to speak? A. And they are sort of a new patient because I don't do partial removals. I do complete removals so the entire pelvis is sort of naïve except with scarring from

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	Page 182		Page 184
1	Q. Okay. And you've been able	1	explanted?
2	when you do these explant surgeries for TVT®,	2	A. So including everything with
3	you've been able to remove all of the mesh?	3	Prolift®?
4	A. Yes.	4	90.
5	Q. All right. Now, so you tried	5	Q. And how many of those have been
6	Prolift® one time.	6	Prolift® versus surgeon-cut Gynemesh® PS?
7	Why did you not like it?	7	A. Surgeon-cut, 15.
8	A. I instantly saw the curling	8	Q. Now, with respect to Gynemesh®
9	similar to what would happen with a TVT®	9	PS, which is what your report is about here,
10	because, again, the same concept.	10	okay, so that's about the mesh, right?
11	Q. The curling of the arms?	11	A. Okay.
12	A. The curling of the arms going	12	Q. You're addressing the mesh
13	through and the pulling and the fraying, and	13	that's cut by the surgeon and can be used for
14	you can actually see the tissue get pulled	14	prolapse, true?
15	as you're pulling on the arm to tension it,	15	• •
16		16	•
	you can actually see the rectal tissue	1	Q. Right, that's what your report
17	pulling in with it. I regret not removing it	17	addresses?
18	right then and there.	18	A. Yes.
19	Q. On the one person?	19	Q. Just so we're clear. Exhibit 3
20	A. On that one person.	20	is a reported that's entitled "Gynemesh® PS,"
21	Q. All right. So how many	21	and that is addressing the mesh that can be
22	Gynemesh® PS products have you explanted?	22	cut from a sheet and used to in various
23	A. Does that include Prolift®?	23	surgeries, correct?
24	Q. Is that a Gynemesh® PS product?	24	A. Yes. Just to be clear when we
N. C.	Page 183		Page 185
1	A. Okay. Yes.	1	talk, are we adding Prolift®, or are we
2	Q. Okay.	2	sticking to just the sheet? I'm a little
3	A. In 2015?	3	confused.
4	Q. No well, we'll start there.	4	Q. If I have a Prolift® question,
5	A. I know that number	5	I'll ask you about it.
6	specifically.	6	A. Okay.
7	Q. Okay. Sure.	7	Q. But I'm talking now about
8	A. About 30.	8	Gynemesh® PS, okay. The mesh itself, do you
9	Q. Okay. And were those all	9	believe that that was so unsafe it never
10	Prolift®?	10	should have been sold?
11	A. Yes.	11	A. Yes.
12	There's some Gynemesh® also.	12	Q. Okay. Why is that?
13	Piece Gynemesh®.	13	A. It folds and curls because of
14	Q. That was cut from a sheet?	14	its poor design. It bunches and rolls when
15	A. Yes.	15	it's placed. The vagina is not the anterior
16	Q. All right. So how many of each	16	abdominal wall. And this mesh was designed
17	of those?	17	for the anterior abdominal wall. And in the
18	A. About seven Gynemesh® from a	18	anterior abdominal wall the surgeon can lay
19	square piece, auto made.	19	it nice and flat. That's not the case in the
20	Q. In other words, a surgeon cuts	20	vagina. The vagina is a tubular structure
21	it?	21	
22	A. Yes.	22	and the attachment points create oblique
	Q. And through your career, how	23	stress when you try to secure it. And then the vagina moves very differently. It has
, , .	CA AND DISTRIBUTE VOID CALEEL HOW		me vagma moves very differentiv. It has
23 24	many Gynemesh® PS products have you	24	completely different tensile characteristic

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1	Page 186		Page 188
	requirements than the anterior abdominal	1	Q. Have you ever used it?
2	wall.	2	A. No.
3	It's really a product that	3	Q. Okay. And you believe it's
4	should have never been put in the vagina.	4	unsafe, too?
5	Q. Mesh in general?	5	A. Yes.
6	A. Yes.	6	Q. And is that any others?
7	Q. All right. Not just Gynemesh®?	7	Any other products?
8	A. Mesh in general.	8	A. I was thinking. So there's
9	Q. So I want to make clear on	9	Gynemesh®, there's Boston Scientific, there's
10	that.	10	Coloplast has Restorelle. Let me see who the
11	It's your opinion that mesh in	11	players are. So Boston Scientific Polyform,
12	general should not of any kind should be	12	Ethicon Gynemesh®, and Coloplast Restorelle.
13	used for treatment of prolapse, true?	13	I think that's it.
14	A. Vaginally placed.	14	Q. Do you know surgeons today that
15	Q. Vaginally placed?	15	use polypropylene mesh for vaginally what
16	A. Because there is no mesh that's	16	was the word you used? Vaginal entrance or
17	designed specifically for the mechanical	17	whatever?
18	requirements of the vagina.	18	A. What did I use, support? I'm
19	Q. Okay. In your view, is	19	not sure what I used.
20	Gynemesh® PS the same as the mesh used for	20	Q. For vaginal prolapse repair,
21	hernia repair?	21	going through the vagina, not abdominally, do
22	A. Yes.	22	you know surgeons today that use mesh for
23	Q. Okay. No differences?	23	that type of surgery?
24	A. No.	24	A. So I want to answer the
	Page 187		Page 189
1	Q. So were there companies besides	1	question. I know there's people using it,
2	Ethicon that made mesh for use with prolapse	2	yes.
3	repair?	3	Q. Okay.
4	A. Yes.	4	A. I don't know them personally,
5	Q. Have you used any of their	5	but I know they're using it.
6	products?	6	Q. So I want to make sure I
7	A. Have not.	7	understand your opinion as to why Gynemesh®
	Q. Okay. But you don't believe	8	
8		1	is unsafe and should never have been sold.
9	any product ever made, any mesh product ever	9	One opinion I'm hearing is that
9 10	made, for vaginal repair of prolapse is safe?	9 10	One opinion I'm hearing is that mesh in general is just not compatible with
9 10 11	made, for vaginal repair of prolapse is safe? A. That is correct.	9 10 11	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true?
9 10 11 12	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh	9 10 11 12	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct.
9 10 11 12 13	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal	9 10 11 12 13	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific
9 10 11 12 13 14	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse?	9 10 11 12 13 14	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a
9 10 11 12 13 14 15	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally?	9 10 11 12 13 14 15	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint?
9 10 11 12 13 14 15 16	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed	9 10 11 12 13 14 15 16	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it
9 10 11 12 13 14 15 16	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally?	9 10 11 12 13 14 15 16 17	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even
9 10 11 12 13 14 15 16 17	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant.	9 10 11 12 13 14 15 16 17	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight,
9 10 11 12 13 14 15 16 17 18	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant. A. There are products that are	9 10 11 12 13 14 15 16 17 18 19	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes
9 10 11 12 13 14 15 16 17 18 19 20	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant. A. There are products that are available at the surgeon's discretion to	9 10 11 12 13 14 15 16 17 18 19 20	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes that in certain areas are above a millimeter,
9 10 11 12 13 14 15 16 17 18 19 20 21	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant. A. There are products that are available at the surgeon's discretion to place in the vagina.	9 10 11 12 13 14 15 16 17 18 19 20 21	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes that in certain areas are above a millimeter, in other areas they're not, which enhances
9 10 11 12 13 14 15 16 17 18 19 20 21 22	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant. A. There are products that are available at the surgeon's discretion to place in the vagina. Q. What are those?	9 10 11 12 13 14 15 16 17 18 19 20 21 22	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes that in certain areas are above a millimeter, in other areas they're not, which enhances bridging fibrosis and scarring. The vagina
9 10 11 12 13 14 15 16 17 18 19 20 21	made, for vaginal repair of prolapse is safe? A. That is correct. Q. Now, are there any mesh products on the market today for vaginal repair of prolapse? A. Placed vaginally? May I ask a question? Placed vaginally? Q. That's what I meant. A. There are products that are available at the surgeon's discretion to place in the vagina.	9 10 11 12 13 14 15 16 17 18 19 20 21	One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true? A. Correct. Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint? A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes that in certain areas are above a millimeter, in other areas they're not, which enhances

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1	mesh. Let's see if I wrote anything else.	1	long-term, tape-induced adverse effects.
2	And obviously all the things we	2	You're aware of that
3	mentioned about polypropylene and the chronic	3	conclusion, right?
4	inflammation and the scarring, especially in	4	A. Yes.
5	a vagina, because the vagina shrinks	5	Q. All right. And you did not
6	differently than the anterior abdominal wall.	6	cite that paper in your report concerning
7	The anterior abdominal wall shrinks in the	7	TVT®, correct?
8	plane of which the mesh is placed.	8	A. Yes.
9	Q. You mean when you're doing a	9	Q. All right. And why did you not
10	sling?	10	cite that paper?
11	A. Well, when you're let me	11	A. The paper started with 90
12	back up.	12	patients, ended up with 45.
13	Q. Okay.	13	Q. Followed over 17 years?
14	A. I meant the abdominal wall,	14	A. But it's half the population.
15	when Gynemesh® is placed in the abdominal	15	So what if the other half had a problem.
16	wall. It's in a sheet.	16	Actually I did some calculations and some of
17	Q. Okay.	17	the percentages that he mentions in there are
18	A. But when it's placed in the	18	not accurate. He's using he's not
19	vagina, it's curvilinear. So just like scar	19	using the 90, he's using less than 90, and
20	will shrink a little bit, it will shrink in a	20	it ends up being a higher percentage than
21	way that will make the vagina not functional.	21	what it should be.
22	Q. Does the mesh actually shrink,	22	So I had some issues about the
23	or is the contraction connected with the	23	paper, and the calculations were off. Half
24	formation of scar tissue?	24	the patients were gone. It wasn't the
	Page 191		Page 193
1	A. The whole unit shrinks. It's a	1	paper would be much more meaningful if
2	combination of the bridging fibrosis, even	2	95 percent of the patients were there
3	scar without mesh is going to shrink. But if	3	followed up.
4	you add chronic inflammation to it and you	4	Q. But you don't have any papers
5	add an attachment point and it pulls	5	cited in your report about TVT® that reached
6	together, it's going to shrink. It's not	6	a contrary conclusion that TVT® had a low
7	that the it's not that the fiber in the	7	satisfaction rate with serious long-term,
8	mesh shrinks. It's not like the	8	taper-induced adverse effects?
9	polypropylene itself is going to shrink. But	9	Do you have any of that any
10	the gaps between the polypropylene shrink.	10	papers to that effect cited in your report,
11	Q. That's part of the scarring	11	true?
12	process?	12	A. Would you repeat that last
13	A. And the bridging fibrosis from	13	sentence?
14	chronic inflammation.	14	Q. You don't have any papers cited
15	MR. MATTHEWS: When you get to	15	in your report that says TVT® does not have a
16	a break point.	16	satisfaction rate and has serious long-term,
17	MR. BALL: Sure, we can do that	17	adverse effects?
18	right now.	18	A. No.
19	(Off the record at 12:22 p.m.)	19	Q. True?
20	QUESTIONS BY MR. BALL:	20	A. True.
	Q. Doctor, the Nilsson paper from	21	Q. Do you have in your report
21			• • •
21 22	2013 that we referred to earlier concluded	22	cited the Svenningsen from 2013 that
21			• • •

	Page 194		Page 196
1	with a low number of reoperations, even in a	1	option for the treatment of female SUI
2	nonselected cohort of patients?	2	recording a very high cure rate with low
3	Do you have that paper?	3	complications after a ten-year follow-up?
4	A. I would have to look.	4	You're not aware of that
5	Can I see the paper?	5	conclusion?
6	Q. Just asking if you have it	6	A. Many times
7	cited in your report.	7	Q. Are you aware of that
8	A. No, I don't.	8	conclusion?
9	Q. Okay. Why not?	9	A. No.
10	A. I tried to cite every paper	10	Many times TVT® doesn't really
11	that I could get my hands on, look at	11	mean Ethicon TVT®; it's a generic term that
12	everything that was available to me. There's	12	talks about slings in general.
13	thousands and thousands of papers on TVT® and	13	Q. Well, this one says it was
14	slings and et cetera.	14	Ethicon.
15	Q. You don't cite a single paper	15	A. Okay.
16	in your report that gives favorable findings	16	Q. But you're not familiar with
17	with respect to TVT®, true?	17	the study?
18	A. No, I do. I mentioned the	18	A. No.
19	Thomas trial, and it says that in the short	19	Q. And you did not cite it in your
20	term, these patients have good outcomes.	20	report?
21	Now, how many papers do you	21	A. Correct.
22	really need to cite in there that in the	22	Q. And, in fact, did you make a
23	short term the sling works?	23	specific search to see if you could find
24	Q. Yeah, let me ask you this: You	24	studies about the long-term efficacy and
	Q. Tean, let me ask you and Tou		,
	Page 195		Page 197
			rage 171
1	don't have any papers that give favorable	1	concerns related to TVT®, did you make that
1 2		1 2	
	don't have any papers that give favorable		concerns related to TVT®, did you make that
2	don't have any papers that give favorable outcomes for long-term studies on TVT®, true?	2	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper
2	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term	2	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did.
2 3 4	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite.	2 3 4	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper
2 3 4 5	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed long-term follow-up of the retropubic TVT®	2 3 4 5	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes. Q. And decided not to mention it
2 3 4 5 6	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed	2 3 4 5 6	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes.
2 3 4 5 6 7 8	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed long-term follow-up of the retropubic TVT® procedure, and you did not were not familiar with it and did not cite it, true?	2 3 4 5 6 7 8	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes. Q. And decided not to mention it in your report? A. Yes.
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2 3 4 5 6 7 8 9 10	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed long-term follow-up of the retropubic TVT® procedure, and you did not were not familiar with it and did not cite it, true? A. Can I see it again? Q. Well, I'm just asking you if	2 3 4 5 6 7 8 9 10	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes. Q. And decided not to mention it in your report? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed long-term follow-up of the retropubic TVT® procedure, and you did not were not familiar with it and did not cite it, true? A. Can I see it again? Q. Well, I'm just asking you if you cited it in your paper, in your report. A. I didn't cite it. Q. And then there's another paper by Serati, et al., "Tension-Free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at a Ten-Year Follow-Up." Did you cite that paper in your report? A. I don't think so.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes. Q. And decided not to mention it in your report? A. Yes. Q. And you did not find the Serati or the Svenningsen paper? A. Correct. MR. MATTHEWS: Do you have an extra copy of those that I can look at? If you don't mind. MR. BALL: I don't mind. QUESTIONS BY MR. BALL: Q. With respect to Gynemesh® PS, did you make a search for any papers regarding multi-year follow-up with respect to use of Gynemesh® PS products in women for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	don't have any papers that give favorable outcomes for long-term studies on TVT®, true? A. There's not a good, long-term study to cite. Q. Well, this one says long term this Svenningsen paper is termed long-term follow-up of the retropubic TVT® procedure, and you did not were not familiar with it and did not cite it, true? A. Can I see it again? Q. Well, I'm just asking you if you cited it in your paper, in your report. A. I didn't cite it. Q. And then there's another paper by Serati, et al., "Tension-Free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at a Ten-Year Follow-Up." Did you cite that paper in your report? A. I don't think so. Q. Okay. And it concludes the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	concerns related to TVT®, did you make that search in connection with your report? A. Yes, I did. Q. And you found the Nilsson paper or were familiar with the Nilsson paper? A. Yes. Q. And decided not to mention it in your report? A. Yes. Q. And you did not find the Serati or the Svenningsen paper? A. Correct. MR. MATTHEWS: Do you have an extra copy of those that I can look at? If you don't mind. MR. BALL: I don't mind. QUESTIONS BY MR. BALL: Q. With respect to Gynemesh® PS, did you make a search for any papers regarding multi-year follow-up with respect to use of Gynemesh® PS products in women for prolapse?

50 (Pages 194 to 197)

Daquetin 2013 paper cited in your Gynemesh® report? 2				
2 report? 3 A. Let me take a look. 4 Doesn't look like that I do. 5 Q. Do you have the so you're 6 not aware of the conclusion from that report, 7 in that study? 8 A. No. 9 Q. Do you have cited in your paper 6 the Landesherr 2012 publication paper, study, 10 surgical intervention after transvaginal 11 Prolift® mesh repair, retrospective 12 single-center study including 524 patients 13 single-center study including 524 patients 14 with three years median follow-up. 15 Did you have that study cited 16 in your 17 A. I excluded studies that had 18 Prolift® because I was not writing a report 19 on Prolift®. 20 Q. Well, isn't Prolift® made from 21 Gynemesh® PS? 22 A. There's a world of difference 23 between Prolift® and Gynemesh® PS. 24 Q. Excuse me, is Prolift® made 25 between Prolift® and Gynemesh® PS. 26 Q. Do you cite multiple internal 27 company documents referring to Prolift®? 28 true? 29 A. That's correct. Because 29 MR. MATTHEWS: Well, let me 20 finish his answer. 21 finish his answer. 22 THE WITNESS: Because there's a 23 world of difference between adding 24 arms that extend into the levators and 25 method of difference between adding 26 method to difference between adding 27 true? 28 A. That's correct. Because 29 MR. MATTHEWS: Well, let me 20 finish his answer. 21 G. But you did not cite any 22 internal follow-up. 23 by the prolift® devices and the single pice that 24 doesn't have arms sexerted. 25 G. Do you think it's 26 control the force sexered that are on that 27 mesh as opposed to a small piece that 28 doesn't have arms exerted. 29 Q. So you don't cite any 29 independent literature relating to Prolift®, true? 30 method of difference between adding 31 doesn't have arms exerted. 32 go bo you cite multiple internal 33 world of difference between adding 44 arms that extend into the levators and 45 the forces exerted that are on that 46 mesh as opposed to a small piece that 47 doesn't have arms exerted. 48 QUESTIONS BY MR. BALL: 49 G. Well, then why did you put all 40 of the Prolift® tunderstand		Page 198		Page 200
A. Let me take a look. Doesn't look like that I do. Q. Do you have the so you're not aware of the conclusion from that report, in that study? A. No. Do you have cited in your paper the Landesherr 2012 publication paper, study, surgical intervention after transvaginal Prolift® mesh repair, retrospective in your Did you have that study cited in your Did you have that study cited in your Did you have data study cited in your Did you have that study cited Is that scientifically appropriate to cherry-pick on what Prolift® documents and literature you use? Between Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® because How as not writing a report on Prolift® and your bink it's scientifically appropriate to cherry-pick on what Prolift® documents and citerature relating to th	1	Jacquetin 2013 paper cited in your Gynemesh®	1	A. Yes.
Doesn't look like that I do. Q. Do you have the - so you're not aware of the conclusion from that report, in that study? R. A. No. Q. Do you have cited in your paper, the Landesherr 2012 publication paper, study, surgical intervention after transvaginal Prolift® mesh repair, retrospective single-center study including 524 patients with three years median follow-up. Did you have that study cited in your Prolift® mesh exase I was not writing a report on Prolift®. A. Texcluded studies that had Prolift® because I was not writing a report on Prolift®. A. There's a world of difference between Prolift® made from Q. Excuse me, is Prolift® made Page 199 Tom Gynemesh® PS? A. Yes. Q. Do you cite multiple internal company documents referring to Prolift®, true? A. Yes. Q. Do you cite multiple internal Company documents referring to Prolift®, true? A. That's correct. Because Q. And yet you don't cite any independent literature relating to Prolift®, true? A. That's correct. Because Q. MR, MATTHEWS: Well, let me Thish his answer. THE WITNESS: Because there's a world of difference between adding A. That's correct. Because Q. Swhy did you cite numerous internal documents and testimony concerning - in fact, you cited studies, the clinical study reports. The with three years and the bladder without arms and have that same clinical consequence with arms. Those were Prolift® devices, Those were Prolift® devices, Those were Prolift® devices, Those were Prolift® devices, The prolift® devices, The prolift® devices, The prolift® devices, Toward of difference between adding, The prolift® devices, The prolift®	2	report?	2	Q. Okay. You cited those. You
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6 not aware of the conclusion from that report, 7 in that study? 8 A. No. 9 Q. Do you have cited in your paper 10 the Landesherr 2012 publication paper, study, 11 surgical intervention after transvaginal 12 Prolift® mesh repair, retrospective 13 single-center study including 524 patients 14 with three years median follow-up. 15 Did you have that study cited 16 in your 17 A. I excluded studies that had 18 Prolift® because I was not writing a report 19 on Prolift®. 20 Q. Well, isn't Prolift® made from 21 Gynemesh® PS? 22 A. There's a world of difference 23 between Prolift® and Gynemesh® PS. 24 Q. Excuse me, is Prolift® made 25 A. Yes. 26 Q. And yet you don't cite any 27 independent literature relating to Prolift®, 28 true? 29 A. That's correct. Because 20 MR, MATTHEWS: Well, let me 21 finish his answer. 22 THE WITNESS: Because there's a 23 world of difference between adding 24 arms that extend into the levators and 25 the forces exerted that are on that 26 mesh as opposed to a small piece that 27 doesn't have a many and the bladder without arms and latting 28 mesh & Special Study reports. 29 Q. Swhy did you cite numerous 20 internal documents and restrance with arms. 20 G. Well, then why did you put all 21 mesh as opposed to a small piece that 22 doesn't have a small piece that 23 doesn't have a rams exerted. 24 g. For indiventional trams and distinct and the bladder without arms and all the 25 clinical study reports. 26 G. Well, then why did you put those in your report? 27 See, I understand that 28 Gynemesh® PS cut from a sheet, you believe, is different than Prolift® literature? 39 Prolift® dicuments and dicin't put in any 30 Prolift® dicuments and didir't put in any 31 Prolift® dicuments and didir't put in any 32 Prolift® dicuments and didir't put in any 32 Prolift® dicuments and didir't put in any 34 Prolift® literature? That's what I don't	4	Doesn't look like that I do.	4	report, right?
The form Gynemesh@ PS? A. Yes.	5	Q. Do you have the so you're	5	A. I
8	6	not aware of the conclusion from that report,	6	Q. Excuse me, didn't you do that?
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24 understand.				
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	Page 202		Page 204
1	A. Because there's a difference	1	A. I believe so.
2	between the clinical execution of putting in	2	Q. Okay. Did you make in your
3	Prolift® with arms that extend into the	3	in your evaluation in this case, did you
4	levators as opposed to putting in a small	4	consider to some degree internal documents
5	piece of Gynemesh®.	5	and internal data related to Prolift® devices
6	Q. Didn't you refer extensively to	6	made out of Gynemesh® PS?
7	results where Prolift® with arms were put in?	7	A. I considered everything that
8	Look at page 21.	8	was available.
9	A. Yes.	9	Q. Including that?
10	Q. You have extensive discussion	10	A. Yes.
11	of Prolift® of a Gynemesh® PS product with	11	Q. Did you make any search for
12	arms, the Prolift® product, put in. You have	12	literature about these long-term success
13	extensive discussion of that at page 21,	13	rates of Gynemesh® PS when used in Prolift®
14	don't you, sir?	14	devices?
15	A. Yes.	15	Did you make that search?
16	Q. And it goes on over, you have a	16	A. Yes.
17	more extensive discussion at page 22,	17	Q. And did you find these three
18	correct?	18	papers that I have in your search these
19	My only point, Doctor, is that	19	three papers that I mentioned?
20	pages 21 and 22, at least, you have extensive	20	A. I did not find those.
21	discussions of studies done installing	21	Q. Now, in the
22	Prolift® in women, implanting Prolift® in	22	MR. MATTHEWS: Well, I am
23	women, true?	23	sorry. Three papers that you
24	A. And I used those from the point	24	mentioned?
	Page 203		Page 205
1	Page 203	1	Page 205
1	of view of shrinkage of the material.	1	MR. BALL: Jacquetin,
2	of view of shrinkage of the material. Q. Those paragraphs don't say,	2	MR. BALL: Jacquetin, Landesherr
2	of view of shrinkage of the material. Q. Those paragraphs don't say, "The only reason I'm citing this is about	2	MR. BALL: Jacquetin, Landesherr MR. MATTHEWS: Okay.
2 3 4	of view of shrinkage of the material. Q. Those paragraphs don't say, "The only reason I'm citing this is about shrinkage." You start off saying, "An	2 3 4	MR. BALL: Jacquetin, Landesherr MR. MATTHEWS: Okay. MR. BALL: I didn't quite get
2 3 4 5	of view of shrinkage of the material. Q. Those paragraphs don't say, "The only reason I'm citing this is about shrinkage." You start off saying, "An Ethicon clinical study for pelvic prolapse	2 3 4 5	MR. BALL: Jacquetin, Landesherr MR. MATTHEWS: Okay. MR. BALL: I didn't quite get to the third one. The Altman paper is
2 3 4 5 6	of view of shrinkage of the material. Q. Those paragraphs don't say, "The only reason I'm citing this is about shrinkage." You start off saying, "An Ethicon clinical study for pelvic prolapse repair involving the Prolift® showed	2 3 4 5 6	MR. BALL: Jacquetin, Landesherr MR. MATTHEWS: Okay. MR. BALL: I didn't quite get to the third one. The Altman paper is also not mentioned there.
2 3 4 5 6 7	of view of shrinkage of the material. Q. Those paragraphs don't say, "The only reason I'm citing this is about shrinkage." You start off saying, "An Ethicon clinical study for pelvic prolapse repair involving the Prolift® showed serious"	2 3 4 5 6 7	MR. BALL: Jacquetin, Landesherr MR. MATTHEWS: Okay. MR. BALL: I didn't quite get to the third one. The Altman paper is also not mentioned there. QUESTIONS BY MR. BALL:
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Page 208 Page 206 1 is how much do you remove, and two, how are 1 quality of life. They don't have the quality 2 the patients doing. 2 of life that they had before because they've 3 3 Q. Okay. So give me the results been through whatever they've been through. 4 So the way I can answer the 4 under both of them. 5 A. If it's a Prolift® that hasn't 5 question is improved quality of life with 6 pain reduction, about 80 percent of the 6 been revised or manipulated in the office, I 7 can usually get out the vast -- all of the 7 patients have no pain. The other 20 percent have some degree of pain. 8 mesh between the rectum and the vagina. 8 9 The arms, depending how they're 9 They still have their prolapse. 10 10 placed, because there's variable there. For Their prolapse comes back. For the 11 11 example, in the one I just took out a few posterior. 12 days ago from my friend Dave Robinson, I 12 For the anterior, it's a little removed the woman's entire right arm out of 13 13 bit less because there's more arms. the gluteus muscles. On her left side, I 14 14 O. A little bit less what? 15 removed half the arm. Almost invariably 15 A. Improvement. 70 to 75 percent. 16 these patients are pain free after surgery. 16 Q. Have pain go away? Not 100 percent. And you can't get 17 A. The pain goes away. 17 18 100 percent of the mesh out. The other 25 percent still have 18 19 You can get more of the 19 some pain. 7 percent of the women have a 20 Prolift® out posteriorly. The anterior 20 scarred, narrowed, foreshortened vagina, and 21 Prolift® you can, again, remove most of the 21 there's all kinds of variations of residual 22 mesh from between the vagina and the bladder. 22 prolapse that occurs. 23 The arms that go around the descending pubic 23 Q. When you do the explant 24 ramus, they're very hard to get. About 24 procedure, do you have to deal with the Page 207 Page 209 50 percent of the time you can remove the 1 1 recurrent prolapse? 2 distal arm and about 20 percent of the time 2 A. Not at that moment. You can't. 3 you can remove the entire apical arm. 3 The dissection is extensive to remove it. 4 If it's a total Prolift® and 4 Q. On most of the patients you 5 5 that bridge of mesh between the anterior and see, do they need a follow-up surgery for 6 posterior have combined together, it is a 6 recurrent prolapse? 7 big, wadded, folded, scarred, difficult 7 Yes. A. 8 8 Okay. Is that usually nightmare. Q. 9 performed by you or someone else? 9 So let's take the women having success from a quality of life and pain A. If they return, I'll do it. 10 10 But they don't all come back. 11 standpoint. 11 12 Q. The great majority of the What is your percentage of 12 success with explant surgery on Gynemesh® 13 13 patients need -- after the mesh is removed, still need treatment for prolapse, surgical 14 products? 14 15 A. Could you ask the question 15 treatment? 16 again differently? 16 A. Some. I don't have an exact 17 Q. Yeah. 17 number. These patients live many states 18 With respect to women from 18 away, and they're seeking my services for 19 becoming an improvement in quality of life 19 removing the mesh and then they may go 20 and not having ongoing problems using --2.0 somewhere else. 21 defining that as success, what is your 21 But your estimate would be the 22 success rate with explanting Gynemesh® 22 great majority of them will need treatment 23 for recurrent prolapse? products? 23 The great majority of them have 24 A. So they have an improved 24

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	Page 210		Page 212
1	prolapse. I don't know if they'll seek	1	A. I think that's a good question.
2	treatment.	2	Q. You've only said that twice
3	Q. Prolapse of grade 2 or greater?	3	today. I hope I have asked more than two
4	A. One segment, two segments,	4	good questions.
5	some, yes.	5	A. So the vast majority of
6	Q. So let's get away from the	6	surgeons will do a sacrocolpopexy and tunnel
7	explant now and just talk to women that come	7	between the vagina and the rectum
8	to you needing surgical treatment for	8	abdominally. That's still placing the mesh
9	prolapse.	9	vaginally. They may think there's an
10	All right. What alternatives	10	advantage because there's no incision.
11	do you offer them?	11	That's not been my experience. Those women
12	•	12	· · · · · · · · · · · · · · · · · · ·
	,	13	still have problems because of placing that
13	repair, cystocele, rectocele, I just use		mesh that way.
14	native tissue.	14	So what I do is I limit the
15	If they need an apical	15	mesh to the apex. So the lancing had three
16	procedure, I will use polypropylene or	16	levels: Apex, middle vagina, and distal
17	suture.	17	vagina. So a TVT® is on the distal anterior
18	Q. So if they need a posterior,	18	segment, and the sacrocolpopexy is on the
19	anterior repair, you'll use what?	19	apex. I only place 2 centimeters on each
20	A. Just native tissue. Absorbable	20	side of the Y. So in total, I place
21	sutures.	21	4 centimeters of mesh by 3 centimeters. So a
22	Q. And if they need an apical	22	very, very small piece.
23	repair, is that an abdominal procedure?	23	Q. So it's two pieces that are 2
24	A. Yes.	24	centimeters by 3 centimeters?
	Page 211		Page 213
1	Q. And you'll use mesh with that?	1	A. No.
2	Q. And you'll use mesh with that?A. Yes.	2	A. No. Q. Okay. I'm sorry.
2 3	Q. And you'll use mesh with that?A. Yes.Q. And what kind of mesh?		A. No.Q. Okay. I'm sorry.A. It's a Y and at the crux of the
2 3 4	Q. And you'll use mesh with that?A. Yes.Q. And what kind of mesh?A. I use BARD Alyte.	2 3 4	A. No.Q. Okay. I'm sorry.A. It's a Y and at the crux of theY is 2 centimeters. So if you laid it open,
2 3	Q. And you'll use mesh with that?A. Yes.Q. And what kind of mesh?A. I use BARD Alyte.Q. How does that differ from	2 3	 A. No. Q. Okay. I'm sorry. A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part
2 3 4	Q. And you'll use mesh with that?A. Yes.Q. And what kind of mesh?A. I use BARD Alyte.	2 3 4	A. No. Q. Okay. I'm sorry. A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part 3 centimeters, and it's actually a circle.
2 3 4 5	 Q. And you'll use mesh with that? A. Yes. Q. And what kind of mesh? A. I use BARD Alyte. Q. How does that differ from Gynemesh® PS? A. The grams per meter squared of 	2 3 4 5 6 7	 A. No. Q. Okay. I'm sorry. A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part 3 centimeters, and it's actually a circle. Q. So it's a circle of mesh?
2 3 4 5 6	 Q. And you'll use mesh with that? A. Yes. Q. And what kind of mesh? A. I use BARD Alyte. Q. How does that differ from Gynemesh® PS? 	2 3 4 5 6	A. No. Q. Okay. I'm sorry. A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part 3 centimeters, and it's actually a circle. Q. So it's a circle of mesh? I'm just trying to get the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And you'll use mesh with that? A. Yes. Q. And what kind of mesh? A. I use BARD Alyte. Q. How does that differ from Gynemesh® PS? A. The grams per meter squared of Gynemesh® is 45. The grams per meter squared for the vaginal arms of the Alyte is 17. So it's very light. And that's less that's about a third of the weight. The pores are much larger. The filaments are much smaller, and even there, I still sew the graft apart to increase the pore size. Q. And what is the size of the mesh, once you is this cut from a sheet, the stuff you use for the ASC? A. Yes. Q. This is for an abdominal A. Yes. Q sacrocolpopexy, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. No. Q. Okay. I'm sorry. A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part 3 centimeters, and it's actually a circle. Q. So it's a circle of mesh? I'm just trying to get the piece of mesh that you cut out before you put it in, how big that? A. It's very, very small. Q. How big? A. It's a circle that has a diameter of 3 centimeters. Q. Okay. All right. So not all ASCs are done abdominally, is that what I just heard you say? A. No, all ASCs are done abdominally. They don't all use mesh. Q. Okay. You're talking about not all apical repairs are done abdominally? A. Yes.
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Page 214 Page 216 1 native tissue repairs for anterior prolapse? 1 really is skewed because there's not a single 2 Would you ask the question 2 paper in the literature, not one, that looks 3 3 at outcomes of native tissue that addresses again? 4 4 the anterior, the apex, the enterocele, the Q. Yeah. 5 What in the medical community 5 rectocele, and the perineum. Not a single 6 in your opinion is recognized as the success 6 paper. 7 7 rate for anterior prolapse when you use Q. So if someone repairs an 8 8 native tissue repairs? anterior prolapse and repairs the apical at 9 What's quoted is 70 percent 9 the same time, do you have an opinion as to A. success. 10 10 what the success rate is? 11 Q. Okay. What do you tell 11 A. Of the anterior and the apical, 12 patients? 12 yes. If it's a good repair and it holds, it 13 13 shouldn't come back. A. I tell them the reason there's 14 only 70 percent success is they have other 14 Q. No, what is the recurrence defects that didn't get fixed. So the 15 rate, I should say? 15 16 patient returns with prolapse because rarely 16 A. I'm not sure I understand the do you have -- and there is a paper out there 17 17 question. 18 that says there's no such thing as a 18 In the medical community if you 19 cystocele, that all cystoceles have an apical 19 do an anterior prolapse repair and at the component. So if you're only fixing the 20 same time do a repair apically with native 20 21 tissue, is there a recognized recurrence rate 21 cystocele, you're going to get an apical 22 22 component. for that? 23 Now, the Altman paper does say 23 A. Yes. 24 that if you put mesh anteriorly on a 24 What is that? Q. Page 215 Page 217 1 cystocele, it does better if you do native 1 It's 10 percent maybe. 2 tissue. However, how many of those patients 2 Okay. So if I'm understanding 3 really would have done well with a native 3 what you're saying is the reason that tissue repair with an apical component. The 4 there -- and you know there's numbers lower 4 5 5 reason -than 70 percent reported in the literature 6 6 for native tissue repair recurrence, right? Q. You mean a native tissue apical 7 component as well as the anterior? 7 A. Yes, but I answered the 8 8 Yes. question truthfully on what I thought was --A. 9 9 O. Okav. Q. No, I'm not quarrelling with 10 10 So that is well-documented that you. 11 there are patients that have a cystocele, but 11 The 30 percent recurrence rate 12 really it's a displacement cystocele, and 12 with anterior repair, you're saying that is 13 it's displaced because the top of the vagina 13 largely caused because an apical repair isn't 14 is coming down as opposed to a distension. 14 done at the same time? 15 So on a distension, sure, you 15 A. Because the patient had a 16 could do a native tissue repair and you're 16 combined defect, only one got fixed. 17 going to get a much higher success rate than 17 Q. Now, how about posterior 18 if you have a displacement cystocele. If you 18 repair, what is the recognized recurrence 19 19 have a displacement cystocele, if you don't rate on a posterior repair, native tissue? 20 do an apical component with the anterior 20 A. 15 to 20 percent. 21 repair, you're absolutely going to have a 21 Q. Is that affected at all by 22 recurrence. So then that's counted as a 22 doing the apical at the same time? 23 recurrence of the cystocele. 23 A. Oh, yes. 24 So that 70 percent success 24 Same deal?

	Page 218		Page 220
1	A. And the perineum.	1	serve?
2	Q. Now, you said is the only	2	A. It's a suspension point so that
3	alternative you talk with patients about is	3	when the vagina tries to evert, it holds it
4	native tissue repair?	4	in position.
5	A. For the cystocele and	5	Q. Is acute or chronic pain a
6	rectocele.	6	potential complication with a native tissue
7	Q. Okay. So if you're doing an	7	repair?
8	apical repair, are you doing this thing with	8	A. No.
9	the small piece of mesh?	9	Q. Or an apical repair of the type
10	A. If I'm doing it abdominally.	10	you described?
11	Q. Okay. Is that what you usually	11	A. No.
12	do?	12	Q. Is acute or chronic pain with
13	A. I do both, vaginally,	13	intercourse a potential complication of a
14	abdominally.	14	native tissue repair or the type of apical
15	Q. What I'm trying to figure out	15	repair you perform?
16	when you're talking to a patient that has an	16	A. Yes, but typically when you do
17	anterior cystocele, do you tell them	17	native tissue repair, the reason you have
18	typically, typically, "I'm going to do a	18	pain with intercourse is because you made the
19	native tissue repair with respect to the	19	vagina too tight at the opening. So it's a
20	anterior prolapse, but we're also doing	20	consequence of a mismatch between the
21	apical repair at the same time"?	21	husband's anatomy and the woman's anatomy.
22	Is that what you say typically?	22	Q. Okay. Because the surgeon made
23	A. If it's a distension cystocele,	23	the vagina too small when they did the native
24	so left to right, okay, what we do when we	24	tissue repair?
	- 010		
	Page 219		Page 221
1	fix a distension cystocele, we basically	1	A. Yes. Or the skin just got
2	fix a distension cystocele, we basically just you have a piece of canvas across the	1 2	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy
2 3	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All		A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the
2 3 4	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures.	2	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's
2 3 4 5	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay.	2 3 4 5	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed.
2 3 4 5 6	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay.	2 3 4 5 6	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential
2 3 4 5 6 7	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a	2 3 4 5 6 7	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair?
2 3 4 5 6 7 8	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a displacement, you got to pull the top up.	2 3 4 5 6 7 8	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair? A. Yes.
2 3 4 5 6 7 8	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a displacement, you got to pull the top up. Otherwise you'll shorten the vagina.	2 3 4 5 6 7 8	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair? A. Yes. Q. Is infection a potential
2 3 4 5 6 7 8 9	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a displacement, you got to pull the top up. Otherwise you'll shorten the vagina. Q. And the pulling the top up is	2 3 4 5 6 7 8 9	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair? A. Yes. Q. Is infection a potential complication with native tissue repair?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a displacement, you got to pull the top up. Otherwise you'll shorten the vagina. Q. And the pulling the top up is what you use the mesh for? A. Yes. Q. Okay. And you may do that either vaginally or abdominally? A. There is a vaginal procedure called the sacrospinous which attaches the top of the vagina to the sacrospinous ligament. Q. And you use mesh in connection with that? A. I use sutures or mesh. Q. And what mention if you're using it either for the ASC or the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair? A. Yes. Q. Is infection a potential complication with native tissue repair? A. Very, very rarely. Q. Well, infection is a very rare complication with Gynemesh® repair as well, true? A. No. Q. What is the percentage of infection with Gynemesh® repair? A. Every woman that has an exposure has an active infection in that tissue. Q. Urinary problems of frequency, urgency, dysuria, obstruction, retention and incontinence, is that a potential
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	fix a distension cystocele, we basically just you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures. Q. Okay. A. Okay. If it has a distension and a displacement, you got to pull the top up. Otherwise you'll shorten the vagina. Q. And the pulling the top up is what you use the mesh for? A. Yes. Q. Okay. And you may do that either vaginally or abdominally? A. There is a vaginal procedure called the sacrospinous which attaches the top of the vagina to the sacrospinous ligament. Q. And you use mesh in connection with that? A. I use sutures or mesh. Q. And what mention if you're	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed. Q. Is vaginal scarring a potential complication of native tissue repair? A. Yes. Q. Is infection a potential complication with native tissue repair? A. Very, very rarely. Q. Well, infection is a very rare complication with Gynemesh® repair as well, true? A. No. Q. What is the percentage of infection with Gynemesh® repair? A. Every woman that has an exposure has an active infection in that tissue. Q. Urinary problems of frequency, urgency, dysuria, obstruction, retention and

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13 Q. Dysuria? 14 A. No. 15 Q. Retention? 16 A. No. 17 Q. Obstruction? 18 A. No. 18 A. No. 19 Q. Incontinence? 20 A. Yes. 21 Q. Is organ or nerve damage a potential complication of native tissue repair? 24 A. Yes. 25 Q. Bleeding, is that a potential 2 complication? 2 A. Yes. 3 A. Yes. 4 Q. Wound complications? 5 A. Yes. 6 Q. Inflammation? 7 A. Yes. 8 Q. Fistula formation? 9 A. Yes. 10 Q. Pelvic floor neuromuscular 11 pain? 12 A. Yes. 13 percentage rate, if it's not done correctly. 14 Q. Do you have an opinion as to with Gynemesh® PS? 17 A. No. 18 Q. Do you have an opinion as to with Gynemesh® PS? 19 what the percentage of recurrent prolapse is with Gynemesh® PS? 20 A. It's less than native tissue repair; but the number of complications and repair repair from mesh problems is much more applications? 2 The pair is the generally recognized number of complications? 3 A. Yes. 4 Q. Wound complications? 4 What is the you said about a solution and repair is the generally recognized number with from the problems is much more applications? 4 What is the you said about a solution and repair is the generally recognized number with from the problems is much more applications? 4 What is the you said about a solution and repair is the generally recognized number with Gynemesh®? 4 What is the generally recognized number with Gynemesh®? 5 A. Yes. 5 Q. Fistula formation? 6 Q. A piece of Gynemesh®? 7 A. Yes. 9 A. 25. 10 Q. Pelvic floor neuromuscular 11 pain? 11 A. (Witness nods head.) 12 Q. What is it with Prolift®, which is made out of Gynemesh®? 13 Q. Lower extremity pain? 14 A. No. 15 Q. Is recurrent surgery a potential risk of native tissue repair? 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 condition and 20 propertial in the second part of your answer.		Page 222		Page 224
that not right? A. Well, not all of them. A. Well, not all of them. A. Well, let's go down them. A. Okay. G. Is urinary frequency a B potential complication of native tissue repair? A. No. G. Well, let's go down them. A. Okay. G. Is urinary frequency a B potential complication of native tissue repair? D. A. No. C. Urgency? D. A. No. C. Well, let's go down them. A. Okay. A. Okay. A. No, C. Okay. Now, well, won't you get some contraction from scarring even with a properly performed native tissue repair? A. No. C. Okay. Now, well, won't you get some contraction from scarring even with a properly performed native tissue repair? A. No. C. Do you have an opinion as to what the percentage rate, if it's not done correctly. C. Do you have an opinion as to what the percentage is of erosion or exposure with Gynemesh® PS? A. Yes. C. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® PS? A. Yes. C. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® PS? A. Yes. C. Wound complication of native tissue repair? A. Yes. Page 223 D. Bleeding, is that a potential complications? A. Yes. C. Wound complications? A. Yes. D. Bleeding, is that a potential complication? A. Yes. D. What is the — you said about a 30 percent recurrence rate with native tiss repair is the generally recognized figure for recurrence of prolapse with Gynemesh®? A. A piece of Gynemesh®? A. Yes. C. Do you have an opinion as to what the percentage of recurrence of prolapse is with Gynemesh®? A. It's less than native tissue repair perair is the generally recognized number of complications and recognized figure for recurrence of prolapse is proper to precure the proper percentage of precurrent prolapse is with Gynemesh®? A. Yes. D. Bleeding of them. A. Yes. D. Bleeding of the microsic percurrent prolapse is with Gy	1	A. There's a whole list there.	1	A. Yes.
that not right? 4			2	Q. Contraction or shrinkage of
4 A. Well, not all of them. 5 Q. Well, let's go down them. 6 A. Okay. 7 Q. Is urinary frequency a 8 potential complication of native tissue repair? 10 A. No. 11 Q. Urgency? 11 Q. Urgency? 12 A. No. 13 Q. Dysuria? 14 A. No. 15 Q. Retention? 16 A. No. 17 Q. Obstruction? 18 A. No. 19 Q. Incontinence? 19 Q. Incontinence? 20 A. Yes. 21 Q. Is organ or nerve damage a repair? 22 potential complication of native tissue repair? 23 q. Yes. 24 A. Yes. 25 Q. Bleeding, is that a potential complication? 26 Q. Inflammation? 27 A. Yes. 28 Q. Inflammation? 38 A. Yes. 49 Q. Wound complications? 40 Q. Inflammation? 40 Q. Pelvic floor neuromuscular pain? 41 A. No. 42 Q. Dysuresh® Ps? 43 Q. Posee of Gynemesh®? 44 Q. Wound complication? 45 A. Yes. 46 Q. Inflammation? 47 A. Yes. 48 Q. Fistula formation? 49 A. Yes. 40 Q. Wound romplication? 40 Q. Pelvic floor neuromuscular pain? 41 A. No. 42 Q. Okay. We'll break that out. 42 Spercent? 43 Page 223 44 Q. Wound complications? 45 A. Yes. 46 Q. Inflammation? 46 A. No. 47 A. Yes. 48 Q. Fistula formation? 49 A. Yes. 40 Q. Wound complications? 40 Q. Pelvic floor neuromuscular pain? 41 A. No. 42 Q. Okay. We'll break that out. 43 potential risk of native tissue removes to much tissue. Premoves to much tissue. Premoves to much tissue. Properly performed native tissue repair? 4 A. No. 4 Q. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® Ps? 4 A. It's less than native tissue repair is the generally recognized number with at the proper of prolapse is with Gynemesh®? 4 A. Yes. 5 Q. Dependential fish of native tissue repair? 5 A. Yes. 6 Q. Inflammation? 7 A. Yes. 9 Q. 2 Spercent? 10 Q. Pelvic floor neuromuscular 11 Q. Lower extremity pain? 12 A. Yes. 13 Q. Down that is the propension of prolapse is with Gynemesh®? 14 A. No. 15 Q. Dependential fish of native tissue repair? 16 Q. Dependential formation? 17 A. Yes. 18 Q. Foreign body response from sutures, is that a potential complication of native tissue repair? 19 Q. That's what I heard in the second part of you		-	3	
Solution			4	a potential risk of native tissue repair?
6 A. Okay. 7 Q. Is urinary frequency a potential complication of native tissue potential complication of native tissue repair? 10 A. No. 11 Q. Urgency? 11 d. A. No. 12 A. No. 13 Q. Dysuria? 14 A. No. 15 Q. Retention? 16 A. No. 17 Q. Obstruction? 18 A. No. 19 Q. Incontinence? 20 A. Yes. 21 Q. Is organ or nerve damage a potential complication of native tissue repair? 22 potential complication of native tissue repair. 23 repair? 24 A. Yes. 25 Q. Bleeding, is that a potential complication? 26 Q. Inflammation? 27 A. Yes. 28 Q. Inflammation? 29 A. Yes. 20 Q. Inflammation? 30 A. Yes. 40 Q. Wound complication? 41 Q. Wound complication? 42 Q. Doyou have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® PS? 41 Q. Bleeding, is that a potential complication of native tissue repair; but the number of complications and reoperations from mesh problems is much me quantity. 41 Q. Wound complications? 42 Q. Okay. We'll break that out. 43 Q. Okay. We'll break that out. 44 Q. Wound complications? 45 A. Yes. 46 Q. Inflammation? 47 A. Yes. 48 Q. Firstula formation? 49 A. Yes. 40 Q. Pelvic floor neuromuscular pain? 41 A. No. 41 Page 223 41 Q. Pelvic floor neuromuscular pain? 41 A. No. 42 Q. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh PS? 41 What is the you said about a 30 percent recurrence rate with native tiss repair is the generally recognized number of complications and reoperations from mesh problems is much me quantity of the properation from mesh problems is much me quantity of the properation from mesh problems is much me quantity of the properation from mesh problems is much me quantity of the properation from mesh problems is much me quantity of the properation from mesh problems is much me properation from mesh problems is much me quantity of the properation from mesh problems is much me properation from mesh problems is much me quantity of the properation from mesh problems is much me quantity of the properation of Gynemesh®? 4 Q. Department of the	5	•	5	A. Yes, but only if the surgeon
8 potential complication of native tissue repair? 10 A. No. 11 Q. Urgency? 11 G. A. No. 12 G. Dysuria? 13 Q. Dysuria? 14 A. No. 15 Q. Retention? 16 A. No. 17 Q. Obstruction? 18 A. No. 19 Q. Incontinence? 20 A. Yes. 21 Q. Is organ or nerve damage a potential complication of native tissue repair? 22 A. Yes. 23 Page 223 1 Q. Bleeding, is that a potential complications? 3 A. Yes. 4 Q. Wound complications? 4 Q. Wound complications? 4 A. Yes. 5 Q. Fistula formation? 6 Q. Fistula formation? 7 A. Yes. 8 Q. Fistula formation? 9 A. Yes. 10 Q. Pelvic floor neuromuscular potential risk of native tissue repair? 10 A. No. 11 A. No. 12 D. Okay. We'll break that out. 11 C. What is the you said about a 30 percent recurrence rate with native tiss repair is the generally recognized number What is the generally recognized number What is the generally recognized number What is the generally recognized figure for recurrence of prolar with Gynemesh®? 12 A. Yes. 13 Q. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® PS? 14 A. Yes. 15 A. Yes. 16 Q. Bleeding, is that a potential complications? 17 A. Yes. 18 Q. Fistula formation? 19 A. Yes. 20 Q. Pelvic floor neuromuscular pain? 21 A. Yes. 22 The pair of the percentage of recurrence of prolar with Gynemesh. 23 This less than native tissue repair is the generally recognized number what is the generally recognized number what is the generally recognized number what is the generally recognized figure for recurrence of prolar with Gynemesh. 24 Q. Wound complications? 25 A. Yes. 26 Q. Fistula formation? 27 A. Yes. 28 Q. Fistula formation? 29 A. Yes. 29 A. 25. 20 Q. Sepercent? 20 A. Yes. 20 A. Piece of Gynemesh®? 21 A. No. 22 A. Yes. 23 C. Lower extremity pain? 24 A. No. 25 Page 22: 26 C. Then you said the complications and reoperations from mesh problems is much more pair. 29 A. Yes. 20 A. Yes. 21 C. The pour different of the property pair and patential risk of native tissue repair? 29 A. Yes. 20 A. Yes. 21 C. The pour different of the property pai	6		6	removes too much tissue.
8 potential complication of native tissue 9 repair? 10 A. No. 10 11 Q. Urgency? 11 12 A. No. 12 13 Q. Dysuria? 13 14 A. No. 14 15 Q. Retention? 15 16 A. No. 16 17 Q. Obstruction? 17 18 A. No. 18 19 Q. Incontinence? 19 20 A. Yes. 20 21 Q. Is organ or nerve damage a 22 potential complication of native tissue repair? 24 A. Yes. 21 2 Q. Bleeding, is that a potential 2 complication? 23 3 A. Yes. 32 4 Q. Wound complications? 4 Q. Wound complications? 4 Q. Wound complications? 4 Q. Wound complication? 4 A. Yes. 5 Q. Fistula formation? 4 A. Yes. 7 A. Yes. 7 A. Yes. 9 A. Yes. 10 Q. Pelvic floor neuromuscular 1 pain? 1. A. No. 14 A. No. 15 Wint Gynemesh®? 15 Q. Is recurrent promised in material potential risk of native tissue repair is the an optical of Gynemesh®? 11 A. No. 12 A. Yes. 12 Q. Do you have an opinion as to what the percentage is of crosion or exposure with Gynemesh® PS? A. It's less than native tissue repair but the number of complications and recoperations from mesh problems is much mc Q. Okay. We'll break that out. Page 223 Page 223 Page 223 Page 223 Page 223 Page 224 A. Yes. 3 Device of Gynemesh®? 19 A. Yes. 9 A. 25.	7		7	Q. Okay. Now, well, won't you get
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6 Q. Inflammation? 7 A. Yes. 8 Q. Fistula formation? 9 A. Yes. 9 A. Yes. 10 Q. Pelvic floor neuromuscular 11 pain? 12 A. Yes. 13 Q. Lower extremity pain? 14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 20 C. With Gynemesh®? 21 A. A piece of Gynemesh®? 22 A. A piece of Gynemesh®? 23 A. A piece of Gynemesh®? 24 A. A piece of Gynemesh®? 25 Q. A piece of Gynemesh®? 26 A. 25. 27 A. 25 Q. What is it with Prolift®, which is made out of Gynemesh®? 28 A. 18 to 25. 29 A. 25. 20 C. What is it with Prolift®, which is made out of Gynemesh®? 20 Then you said the complications are more, right? 20 Can you give me any percentages			5	
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9 A. Yes. 10 Q. Pelvic floor neuromuscular 11 pain? 11 A. (Witness nods head.) 12 A. Yes. 13 Q. Lower extremity pain? 14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 20 Can you give me any percentages	8		8	
10 Q. Pelvic floor neuromuscular 11 pain? 12 A. Yes. 13 Q. Lower extremity pain? 14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 20 C. What is it with Prolift®, which 21 A. (Witness nods head.) 21 A. (Witness nods head.) 22 P. What is it with Prolift®, which 23 is made out of Gynemesh®? 24 A. 18 to 25. 25 Q. Then you said the complications 26 are more, right? 27 A. Yes. 28 Q. That's what I heard in the 29 second part of your answer. 20 Can you give me any percentages				
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A. Yes. Q. Lower extremity pain? 13 is made out of Gynemesh®? 14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 10 Q. What is it with Prolift®, which 13 is made out of Gynemesh®? A. 18 to 25. Q. Then you said the complications are more, right? A. Yes. Q. That's what I heard in the 19 second part of your answer. Can you give me any percentages			11	- <u>*</u>
13 Q. Lower extremity pain? 14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 13 is made out of Gynemesh®? A. 18 to 25. Q. Then you said the complications are more, right? A. Yes. 17 A. Yes. Q. That's what I heard in the second part of your answer. 20 Can you give me any percentages		-	12	
14 A. No. 15 Q. Is recurrent surgery a 16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 14 A. 18 to 25. Q. Then you said the complications are more, right? A. Yes. 17 A. Yes. Q. That's what I heard in the second part of your answer. 20 Can you give me any percentages			13	
16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 16 are more, right? A. Yes. 17 A. Yes. Q. That's what I heard in the second part of your answer. 20 Can you give me any percentages	14	-	14	
16 potential risk of native tissue repair? 17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 16 are more, right? 17 A. Yes. 18 Q. That's what I heard in the second part of your answer. 20 Can you give me any percentages	15	Q. Is recurrent surgery a	15	Q. Then you said the complications
17 A. Yes. 18 Q. Foreign body response from 19 sutures, is that a potential complication of 20 native tissue repair? 17 A. Yes. 18 Q. That's what I heard in the 19 second part of your answer. 20 Can you give me any percentages	16		16	
sutures, is that a potential complication of 20 second part of your answer. Can you give me any percentages	17	•	17	A. Yes.
sutures, is that a potential complication of 20 second part of your answer. 20 native tissue repair? 20 Can you give me any percentages	18	Q. Foreign body response from	18	Q. That's what I heard in the
20 native tissue repair? 20 Can you give me any percentages	19		19	second part of your answer.
	20		20	Can you give me any percentages
· · · · · · · · · · · · · · · · · · ·	21		21	as the complications with native tissue
Q. Exposure or erosion of sutures, 22 repair versus the complications with	22	Q. Exposure or erosion of sutures,	22	repair versus the complications with
23 is that a potential complication of native 23 Gynemesh® surgery for prolapse?	23		23	Gynemesh® surgery for prolapse?
24 tissue repair? 24 A. Would you ask the question	24	tissue repair?	24	A. Would you ask the question

57 (Pages 222 to 225)

	Page 226		Page 228
1	again?	1	Gynemesh® PS product put in of any kind for
2	Q. Yeah.	2	prolapse, what percentage of them have had
3	You said when I asked you	3	long-term complications?
4	what the comparative recurrence rates were,	4	Do you have an opinion on that?
5	okay, you said, "Well, the recurrence rates	5	A. No.
6	are lower with Gynemesh® for prolapse, but	6	Q. Okay. Do you have an opinion
7	there's more complications."	7	of the percentage of women who have had a
8	Okay. What I'm trying to do is	8	native tissue repair have had long-term
9	figure out how much more.	9	complications?
10	A. Okay.	10	A. Very rare.
11	Q. So what would you say to that?	11	Q. Okay. And have you done any
12	A. So with native tissue repair,	12	literature review to try to determine what
13	the main issue is recurrence, which is why	13	the long-term complications are with over
14	someone at some point thought let's do what	14	a period of years for women who have had a
15	we do in abdominal surgery and put a piece of	15	Gynemesh® PS product used for prolapse?
16	mesh in there.	16	A. I have.
17		17	
18	So what was the question again?		Q. Okay. And have you found any
	The	18 19	literature?
19	Q. How would you compare the risk		A. There is very little papers
20	of complications with Gynemesh® used in	20	that talks about pieces of Gynemesh® put in
21	prolapse repair versus complications from	21	anteriorly or posteriorly.
22	native tissue repair?	22	Q. You're changing my question. I
23	A. So you have a slightly higher	23	said Gynemesh® product.
24	recurrence rate with native tissue. You	24	Okay. So have you done any
	2 000		
	Page 227		Page 229
1	don't have as much contracture. You don't	1	Page 229 literature search to determine any product
1 2	don't have as much contracture. You don't	1 2	
	don't have as much contracture. You don't have scarification. You don't have a foreign		literature search to determine any product that uses Gynemesh® in prolapse repair to
2 3	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign	2	literature search to determine any product
2	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with	2	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications
2 3 4	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is	2 3 4	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes.
2 3 4 5	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an	2 3 4 5	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found?
2 3 4 5 6 7	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with	2 3 4 5 6 7	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in
2 3 4 5 6	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are	2 3 4 5 6	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for
2 3 4 5 6 7 8	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with	2 3 4 5 6 7 8	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications
2 3 4 5 6 7 8	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero.	2 3 4 5 6 7 8	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications
2 3 4 5 6 7 8 9	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you	2 3 4 5 6 7 8 9	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have
2 3 4 5 6 7 8 9 10	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a	2 3 4 5 6 7 8 9 10 11	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a
2 3 4 5 6 7 8 9 10 11 12	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you	2 3 4 5 6 7 8 9 10 11 12	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search.
2 3 4 5 6 7 8 9 10 11 12 13	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with	2 3 4 5 6 7 8 9 10 11 12 13	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers?
2 3 4 5 6 7 8 9 10 11 12 13	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent.	2 3 4 5 6 7 8 9 10 11 12 13 14	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah.
2 3 4 5 6 7 8 9 10 11 12 13 14	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me
2 3 4 5 6 7 8 9 10 11 12 13 14 15	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your report that address the issue of long-term
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the stress yielding that that tissue gets thin	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your report that address the issue of long-term complications with Gynemesh® PS product, any
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the stress yielding that that tissue gets thin and eventually pops through and then it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your report that address the issue of long-term complications with Gynemesh® PS product, any Gynemesh® PS product?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the stress yielding that that tissue gets thin and eventually pops through and then it starts the cycle with infection and erosion	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your report that address the issue of long-term complications with Gynemesh® PS product? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero. If you add anterior if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term. I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the stress yielding that that tissue gets thin and eventually pops through and then it starts the cycle with infection and erosion and vaginal discharge.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are? A. Yes. Q. Okay. And what have you found? A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications Q. No, I meant what papers have you found. I asked if you had done a literature search. A. What papers? Q. Yeah. What papers well, let me back up. Are there any papers in your report that address the issue of long-term complications with Gynemesh® PS product? A. No. Q. Okay. Do you believe that the

	Page 230		Page 232
1	complications connected with Prolift®?	1	how you deal with these complications. But
2	A. Yes.	2	if you're walking on a lake, at the edge of
3	Q. Okay. How much less?	3	the lake it's very thick; you can stand on
4	A little bit? A lot?	4	it. As you get towards the middle, the ice
5	A. A lot less.	5	gets thin. So where it gets thin, you fall
6	Q. Okay. Do you have an opinion	6	through.
7	as to the percentage of erosion exposure with	7	As you move back towards the
8	Gynemesh® PS? Not Prolift®, just Gynemesh®	8	edge, it's better. So the only way to
9	PS.	9	effectively treat these mesh issues is not in
10	A. I'm not sure I understand the	10	the office. It's actually cruel and unusual
11	question.	11	punishment for the woman. It's to take her
12	Q. For Gynemesh® PS used in	12	to the operating room and cut that mesh back
13	prolapse repair, not Prolift®, just Gynemesh®	13	either completely or to a point that the full
14	PS cut out of a sheet, do you have an opinion	14	thickness of the fibromuscular wall of the
15	as to the percentage of exposures or erosions	15	vagina is free of mesh. That is the only
16	that occur with that?	16	way.
17	A. All the information I have is	17	Q. Can some mesh exposures be
18	the patients I see. I don't have a	18	treated without complete removal of the mesh?
19	denominator of how many went in.	19	A. Can the exposure be removed
20	Q. So you don't have a percentage	20	that's visible? Yes, but can it be treated?
21	globally?	21	No, because of what I just explained.
22	A. No.	22	Q. So you're saying any time
23	Q. Okay. Exposures, erosions, can	23	there's a mesh exposure, almost all the mesh
24	they sometimes be asymptomatic?	24	needs to be removed?
	Page 231		Page 233
1	Page 231 A. Yes.	1	Page 233 A. You have to cut it back.
1 2		1 2	
	A. Yes.		A. You have to cut it back.
2	A. Yes.Q. Can they sometimes be treated	2	A. You have to cut it back.Q. It's not what I asked. I'm
2 3	A. Yes. Q. Can they sometimes be treated in the office?	2	A. You have to cut it back. Q. It's not what I asked. I'm just
2 3 4	A. Yes.Q. Can they sometimes be treated in the office?A. No.	2 3 4	A. You have to cut it back. Q. It's not what I asked. I'm just A. No.
2 3 4 5	 A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a 	2 3 4 5	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be
2 3 4 5 6	 A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? 	2 3 4 5 6	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed?
2 3 4 5 6 7	 A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. 	2 3 4 5 6 7	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does.
2 3 4 5 6 7 8	 A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the 	2 3 4 5 6 7 8	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so
2 3 4 5 6 7 8 9 10	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't	2 3 4 5 6 7 8	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining	2 3 4 5 6 7 8 9 10 11 12 13	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter exposure, you should remove all of the mesh? A. The way you're asking the question, I have to answer yes. Q. Okay. Why am I asking it
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining graft as it goes laterally, wherever it goes, is covered by a very thin tissue of epithelium. The epithelium is not living tissue. Even if you trim it back and you make it smooth, that implant is still in the vaginal wall. The only way, effective way	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter exposure, you should remove all of the mesh? A. The way you're asking the question, I have to answer yes. Q. Okay. Why am I asking it wrong? A. Because the way I think as a surgeon is I want to fix this woman. And the way you're asking the question is you want me to do the minimal amount to get past it. So I'm honestly answering that. The treatments
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining graft as it goes laterally, wherever it goes, is covered by a very thin tissue of epithelium. The epithelium is not living tissue. Even if you trim it back and you make it smooth, that implant is still in the vaginal wall. The only way, effective way—and there's no guidance in any of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter exposure, you should remove all of the mesh? A. The way you're asking the question, I have to answer yes. Q. Okay. Why am I asking it wrong? A. Because the way I think as a surgeon is I want to fix this woman. And the way you're asking the question is you want me to do the minimal amount to get past it. So I'm honestly answering that. The treatments that have been set forth in helping these
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining graft as it goes laterally, wherever it goes, is covered by a very thin tissue of epithelium. The epithelium is not living tissue. Even if you trim it back and you make it smooth, that implant is still in the vaginal wall. The only way, effective way—and there's no guidance in any of the literature on how to do this or any of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter exposure, you should remove all of the mesh? A. The way you're asking the question, I have to answer yes. Q. Okay. Why am I asking it wrong? A. Because the way I think as a surgeon is I want to fix this woman. And the way you're asking the question is you want me to do the minimal amount to get past it. So I'm honestly answering that. The treatments that have been set forth in helping these women are a problem, which is why all of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Can they sometimes be treated in the office? A. No. Q. They can't be treated through a procedure in the office? A. Well, let me clarify. Q. Okay. A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining graft as it goes laterally, wherever it goes, is covered by a very thin tissue of epithelium. The epithelium is not living tissue. Even if you trim it back and you make it smooth, that implant is still in the vaginal wall. The only way, effective way—and there's no guidance in any of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. You have to cut it back. Q. It's not what I asked. I'm just A. No. Q. It doesn't have to all be removed? A. Yes, it does. Q. So any time you have a so even if you have like a 10-millimeter exposure, you should remove all of the mesh? A. The way you're asking the question, I have to answer yes. Q. Okay. Why am I asking it wrong? A. Because the way I think as a surgeon is I want to fix this woman. And the way you're asking the question is you want me to do the minimal amount to get past it. So I'm honestly answering that. The treatments that have been set forth in helping these women are a problem, which is why all of these women have all these issues.

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Dionysios K. Veronikis, M.D. Page 234 Page 236 1 Q. So if doctors, surgeons out 1 devastated from what's happened. 2 there, if they, after surgery, three months, 2 Q. Well, I didn't ask about the 3 3 six months later, have a small, 10-millimeter patients you saw. 4 or so exposure, you're saying that what they 4 Do you believe in the world are 5 should do is remove all of the mesh at that 5 there many patients that have benefitted from 6 6 time? Gynemesh® PS being used to treat their 7 7 A. Yes, I would call that big. I prolapse? 8 8 think if there's a couple fibers, you can A. I do not. 9 watch it. There is no evidence whatsoever to 9 Okay. Do you believe there's Q. 10 10 suggest that estrogen helps, but maybe if you any patients in the world that have benefitted from TVT® being used for their 11 rub it in there and you promote some blood 11 12 flow or somehow, it may help with some 12 stress urinary incontinence? 13 13 fibers. A. Some, yes. 14 But once you have -- it's sort 14 Q. Most, true? 15 of like a fistula. When you fix a fistula, 15 Based on the patients that are 16 even though the fistula is 45 millimeters, 16 in the -- that have been followed and based 17 the defect around it, there's probably 17 on all the data that can be transposed to the 18 another circumference of 3 or 4 millimeters, 18 world, okay, if you take Ulmsten's data and 19 which is why fistulas fail when you fix them. 19 you take the Oga position paper, the Oga 20 20 So if you're only removing that paper that is cited on the back of SUFU and 21 21 part that's on the thin ice, the example I AUGS and you look at the grade of the 22 22 used on the lake, the woman is going to have reports, those patients in those studies, 23 a problem because it's in the vaginal wall. 23 they're not high-grade, quality studies, but 24 24 So can you leave maybe a little behind? But there's about 15,000 patients that are Page 235 Page 237 1 1 even when you do, it's been my experience in reported in there. 2 seeing these women that they're going to come 2 So if you extrapolate all that back with pain because the edge now is no 3 data, okay, I would agree that 85 percent of 3 longer flat. The edge now pokes through the 4 the women are cured of their incontinence. 4 5 5 tissue. When the mesh is intact and it's What none of us know is what are the 6 6 flat, you have a sheet of human tissue over long-term consequences. Because when you 7 it, it's not poking her. When you cut it, it 7 look at that paper that's cited on the AUGS, 8 8 is like a sawblade poking at her because the SUFU statement position paper and you really 9 fibers are like sutures poking through. 9 read that paper, it actually talks about 10 Are you aware of any 10 needing long-term data for mesh implants. 11 peer-reviewed literature that supports the 11 Q. And who is the author on that? 12 proposition that regardless of the size of 12 That was Oga. A. 13 the exposure that all mesh should be removed, 13 You don't believe there's any 14 if there's an exposure? 14 safe alternative for the use of mesh -- I 15 A. No. 15 mean, there's no safe use of mesh in the 16 Would you agree that there are 16 vagina for prolapse, true? 17 many patients that have benefitted from 17 A. Not the current mesh that we Gynemesh® PS being used for prolapse? 18 18 have. 19 A. No. 19 Q. Well, you can't identify --20 Are there any? 20 that would be the better way to say it. Q. 21 A. No. 21 You can't identify a mesh

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that's out there on the market that you would

consider to be safe for prolapse repair,

22

23

24

true?

22

23

24

Q. Why do you say that?

patients I see and their lives are totally

It's a very biased view in the

	Page 238		Page 240
1	A. From my reading of the	1	explanted, the filament doesn't show. The
2	documents, I have learned that there is a	2	filament is cracks, the polypropylene shows.
3	mesh that's better than polypropylene,	3	I've read documents that says
4	Pronova.	4	that the preparation of the polypropylene
5	Q. My question was do you know	5	filament through the stretching and the
6	whether it's safe or not?	6	heating creates a core that cools differently
7	A. Based on the information I have	7	than the external, which is why the external
8	and the characteristics of the mesh, it's	8	is subjected to cracking. And there's metals
9	safer.	9	that are used to stabilize it and peroxidases
10		10	during the inflammatory process start to
11	Q. But that wasn't my question whether there was one safer.	11	during the inframmatory process start to degrade it. It's a vicious cycle which is
12	My question is it safe, would	12	why the chronic reaction occurs.
13	you use it in the vagina?	13	Q. Is there any peer-reviewed
14	A. Yes.	14	literature establishing Pronova as a good
15	Q. Okay. Why?	15	product for prolapse repair?
16	What's different about it?	16	A. No.
17	Who makes Pronova, by the way?	17	Q. When you have patients coming
18	A. Ethicon.	18	to you that have had mesh and they're having
19	Q. What's safer about the Pronova?	19	some issues with them, do you always
20	A. So the fibers are completely	20	recommend an explant of the mesh?
21	different. When you look at certain	21	A. Ask the question again, please?
22	studies	22	Q. Yeah.
23	Q. I'm going to have to withdraw	23	Did you have patients coming to
24	and interrupt just a second.	24	you you said from all over that have
	Page 239		D 041
			Page 241
1	Has Pronova been used for	1	had a mesh product implanted in them, do you
2	Has Pronova been used for prolapse repair successfully in studies?	2	had a mesh product implanted in them, do you always recommend explanting of the mesh?
2	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used.		had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No.
2 3 4	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it	2	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not?
2	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for	2	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically
2 3 4	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it	2 3 4	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it.
2 3 4 5	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes.	2 3 4 5	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have
2 3 4 5 6	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair?	2 3 4 5 6	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having
2 3 4 5 6 7	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes.	2 3 4 5 6 7	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have
2 3 4 5 6 7 8	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it	2 3 4 5 6 7 8	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having
2 3 4 5 6 7 8	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies?	2 3 4 5 6 7 8	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would
2 3 4 5 6 7 8 9	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's	2 3 4 5 6 7 8 9	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"?
2 3 4 5 6 7 8 9 10	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility.	2 3 4 5 6 7 8 9 10 11	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes.
2 3 4 5 6 7 8 9 10 11 12	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly	2 3 4 5 6 7 8 9 10 11 12	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under
2 3 4 5 6 7 8 9 10 11 12 13	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe	2 3 4 5 6 7 8 9 10 11 12 13	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances?
2 3 4 5 6 7 8 9 10 11 12 13 14	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair?	2 3 4 5 6 7 8 9 10 11 12 13 14	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is	2 3 4 5 6 7 8 9 10 11 12 13 14 15	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical. It's polyvinylidene fluoride.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure? A. I accept insurance. Whatever
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical. It's polyvinylidene fluoride. Q. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure? A. I accept insurance. Whatever the insurance pays.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical. It's polyvinylidene fluoride. Q. Okay. A. And when they even Ethicon	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure? A. I accept insurance. Whatever the insurance pays. Q. And how many of those do you do
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical. It's polyvinylidene fluoride. Q. Okay. A. And when they even Ethicon themselves has done testing on it, it is a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure? A. I accept insurance. Whatever the insurance pays. Q. And how many of those do you do each year?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Has Pronova been used for prolapse repair successfully in studies? A. Hasn't been used. Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair? A. Yes. Q. Okay. And even though it hasn't been proven in any studies? A. It hasn't been used it's been looked at biocompatibility. Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair? A. The long-term inflammation is reduced. Q. Because? A. It's a different chemical. It's polyvinylidene fluoride. Q. Okay. A. And when they even Ethicon	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	had a mesh product implanted in them, do you always recommend explanting of the mesh? A. No. Q. When do you not? A. When there's nothing clinically that I think I can add by removing it. Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"? A. Yes. Q. Okay. Do you take it out under those circumstances? A. No. Q. Okay. I think there are some that do that, that's why I asked. What is your charge for an explant procedure? A. I accept insurance. Whatever the insurance pays. Q. And how many of those do you do

Ì	Page 242		Page 244
1	implants.	1	A. The elasticity.
2	Q. And before that, it was another	2	Q. Bidirectional elasticity to
3	20 percent or something above that?	3	some degree remains with the Gynemesh® PS
4	A. I think I hit 400 one year, and	4	when it's put in the body?
5	I decreased the number.	5	A. Oh, let me change my answer to,
6	Q. Have you ever had any nerve	6	yes, in the short term.
7	entrapment in any have you ever found any	7	Q. Okay. How much Gynemesh® PS is
8	nerve entrapment as a part of your explant	8	used typically not Prolift®, just
9	procedures?	9	Gynemesh® PS, used for a prolapse repair?
10	A. Yes.	10	How much is used?
11	Q. Rarely?	11	A. Depends where
12	A. Yes.	12	•
13	Q. Okay. How do you know that	13	A. Anteriorly?
14	there's nerve entrapment as you do an explant	14	Depends on the woman's vagina,
15	procedure?	15	but let's say average of 7 centimeters by 6.
16	Is that confirmed by pathology,	16	Q. Okay.
17	or what's your basis for that?	17	A. Maybe and there's longer and
18	A. The TVT® sling was attached to	18	wider depending on the bony structure.
19	the obturator nerve directly, and I touched	19	Q. How about posteriorly?
20	the mesh to free it up and the patient's leg	20	A. The posterior segment tends to
21	jumped.	21	be a little longer. 9 by 5.
22	Q. Was that as a result of a	22	Q. The meshes from other companies
23	surgical technique problem?	23	that use that are used for prolapse, do
24	A. It's a result of the IFU and	24	any of those have bigger pores or lighter
	Page 243		Page 245
1	the directions that's given to the surgeon to	1	weight?
2	use a large trocar.	2	A. I want to make sure I
3	Q. Okay. Was that the only	3	understand the question.
4	occasion you've had a nerve entrapment	4	Q. Yeah.
5	problem?	5	There's other mesh products
6	A. It's been several times. I	6	that can be used for prolapse repair, right?
7	don't like giving an exact number because I	7	A. Yes.
8	don't track all of those things. What I	8	Q. Have any of those had a lighter
9	track is how much I help patients with what I	9	weight or bigger pores than a Gynemesh® PS?
10	do.	10	A. Yes.
	Q. But that was something was	11	
11			
11 12			Q. Okay. Which one?
12	the nerve in the example you gave, was the	12	A. Coloplast is much lighter.
12 13	the nerve in the example you gave, was the nerve entrapment, did that occur was that	12 13	A. Coloplast is much lighter.Q. Okay. And when did that come
12 13 14	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient?	12 13 14	A. Coloplast is much lighter. Q. Okay. And when did that come on the market?
12 13 14 15	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes.	12 13 14 15	A. Coloplast is much lighter.Q. Okay. And when did that come on the market?A. I can't tell you the exact
12 13 14 15 16	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the	12 13 14 15 16	A. Coloplast is much lighter.Q. Okay. And when did that come on the market?A. I can't tell you the exact date. Probably in the last seven, eight
12 13 14 15 16 17	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that.	12 13 14 15 16 17	 A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years.
12 13 14 15 16 17	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has	12 13 14 15 16 17 18	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter
12 13 14 15 16 17 18	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it?	12 13 14 15 16 17 18 19	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter squared?
12 13 14 15 16 17 18 19 20	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it? A. Yes.	12 13 14 15 16 17 18 19 20	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter squared? What's its weight?
12 13 14 15 16 17 18 19 20 21	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it? A. Yes. Q. And it maintains that to some	12 13 14 15 16 17 18 19 20 21	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter squared? What's its weight? A. It's I think it's 27.
12 13 14 15 16 17 18 19 20 21 22	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it? A. Yes. Q. And it maintains that to some degree once it's put in the body, true?	12 13 14 15 16 17 18 19 20 21 22	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter squared? What's its weight? A. It's I think it's 27. Q. And what is Gynemesh® PS?
12 13 14 15 16 17 18 19 20 21	the nerve in the example you gave, was the nerve entrapment, did that occur was that producing symptoms for the patient? A. Yes. Q. Okay. Now, before the Prolift®, when it's strike that. Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it? A. Yes. Q. And it maintains that to some	12 13 14 15 16 17 18 19 20 21	A. Coloplast is much lighter. Q. Okay. And when did that come on the market? A. I can't tell you the exact date. Probably in the last seven, eight years. Q. What's its gram per meter squared? What's its weight? A. It's I think it's 27.

1 peer-reviewed literature that is critical of the pore size or weight of Gynemesh® PS? 3 A. No. 4 Q. Have you ever written in a medical record that a patient had clinical problems resultant to particle loss or degradation? 5 medical record that a patient had clinical problems resultant to particle loss or degradation? 6 problems resultant to particle loss or degradation? 7 degradation? 8 A. No. 9 Q. Did you review the strike 10 that. 11 Lasked you before some 12 questions, and I can't remember whether they were TVT®-related or not, but have you reviewed other warnings information that was given to doctors other than the IFU with respect to Gynemesh® PS products? 17 A. I reviewed everything that was given to me. I don't recall specifically at this time. 19 Q. Do you recall reviewing the surgeon's monograph with respect to the 22 Gynemesh® PS products? 23 A. I don't recall. 24 Q. Did you read the Prolift® IFU 25 A. I did. 26 Q. Whay. And what are those? 27 A. Those are one is a single-incision sling and the Prefyx 28 A. Different. It has plastic arrowheads that attach to the muscles. 29 Q. Yes. 29 A. So which one is that, 29 Q. So you've testified as an expert witness against the Solyx product? 29 A. I don't recall. 29 Q. Do yo recall reviewing the 20 Q. You said that it is never should have been on the market? 20 Q. Did you read the Prolift® IFU 21 when you used it that one time? 22 A. I did. 3 Q. Had you read it since until you became involved in this litigation? 4 Deceme involved in this litigation? 5 A. I read it again. 6 Q. When you became that's what you mean. 8 A. Yes. 9 Q. But the gap of years, you hadn't read it in between? 11 A. I looked at it from time to time. It was a place of the material? 12 A. That's a sling. 13 C. Okay. And what's the problem with it? 14 Well, let me ask you this: On both of those products, have you been critical of the technique described in the IFU? 24 A. Yes. Q. And have you been critical of the technique described in the IFU? 25 A. Yes. 26 Q. And have you bee		Page 246		Page 248
2 the pore size or weight of Gynemesh® PS? 3 A. No. 4 Q. Have you ever written in a 5 medical record that a patient had clinical 6 problems resultant to particle loss or 7 degradation? 7 degradation? 8 A. No. 8 Single-incision sling and the Prefyx 10 that. 11 I asked you before some 12 questions, and I can't remember whether they 13 were TVT®-related or not, but have you 14 reviewed other warnings information that was 15 given to doctors other than the IFU with 16 respect to Gynemesh® PS products? 17 A. I reviewed everything that was 18 given to me. I don't recall specifically at 19 this time. 20 Q. Do you recall reviewing the 21 surgeon's monograph with respect to the 22 Gynemesh® PS products? 23 A. I don't recall. 24 Q. Did you read the Prolift® IFU 25 A. I did. 26 Q. When you became that's what 27 you mean. 28 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And didy ou say you have not 2 C. And what are those? 2 A. Those are one is a single-incision sling and the Prefyx - 2 A. Different. It has plastic arrowheads that attach to the muscles. 2 C. Okay. So which one is that, 2 Solyx or Prefyx? 4 A. Sorry, the single incision. 2 Yes. 2 A. Soyy. 2 A. Soyyo've testified as an expert witness against the Solyx product? 4 A. Yes. 2 Q. Okay. And what are those? 4 A. Yes. 2 Q. Okay. And what are those? 4 A. Yes. 9 Q. When you became that's what you mean. 8 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. Iread al to of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Ava	1		1	
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Somedical record that a patient had clinical problems resultant to particle loss or degradation? Complete problems resultant to particle problems resultant to particle loss or degradation? Complete problems resultant to particle loss or degradation. Complete problems resultant problems resultant problems resultant problems resultant pr				
6 problems resultant to particle loss or degradation? 7 degradation? 8 A. No. 9 Q. Did you review the strike 10 that. 1 I asked you before some 11 I I asked you before some 12 questions, and I can't remember whether they are rVT®-related or not, but have you reviewed other warnings information that was given to doctors other than the IFU with respect to Gynemesh® PS products? 17 A. I reviewed everything that was 17 Q. So you've testified as an expert witness against the Solyx product? 18 given to me. I don't recall specifically at this time. 19 Q. Do you recall reviewing the 20 Q. Do you recall reviewing the 20 Q. Do you recall reviewing the 20 Q. Did you read the Prolift® IFU 24 Q. Did you read the Prolift® IFU 24 When you used it that one time? 22 Gynemesh® PS products? 23 A. I don't recall. 24 Q. Did you read the Prolift® IFU 24 when you used it that one time? 25 A. I did. 26 Q. When you became that's what you mean. 27 A. I did. 29 Q. Okay. And what about Prefyx, what kind of product is that? 28 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 10 hadn't read it in between? 11 A. Those are one is a single-incision sling end the Profyx value are the total to more them. Elevate's different they 20 Q. Okay. So which one is that, Solyx or Prefyx? 29 A. I don't recall specifically at 18 expert witness against the Solyx product? 29 A. I don't recall specifically at 18 expert witness against the Solyx product? 29 A. I don't recall. 20 Q. Do you recall reviewing the 20 Q. You said that it is never should have been on the market? 20 Q. Okay. And what about Prefyx, what kind of product is that? Page 247 1 when you used it that one time? 1 A. That's a sling. 2 A. I't is in front. 2 Q. Okay. Different from retropubic.? 3 A. I't is in front. 4 Q. Okay. Different from retropubic.? 4 A. I't is in front. 5 Q. Okay. And what s't he problem with it? Well, let me ask you this: On both of those products, have you been critical of the technique described in the IFU? 4 A. Yes. Q. And have you				
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Page 247 When you used it that one time? 1	23		23	
1when you used it that one time?1A. That's a sling.2A. I did.2Q. Okay. What kind of sling?3Q. Had you read it since until you3A. Prepubic.4became involved in this litigation?4Q. Okay. Different from5A. I read it again.5retropubic?6Q. When you became that's what6A. It's in front.7you mean.7Q. Okay. And what's the problem8A. Yes.8with it?9Q. But the gap of years, you9Well, let me ask you this: On10hadn't read it in between?10both of those products, have you been11A. I looked at it from time to11critical of the instrumentation?12time. I read a lot of IFUs. As I mentioned12A. Yes.13earlier, I own all of the products because I13Q. Have you been critical of the14have to study them on how they're designed to14technique described in the IFU?15be able to remove them. Elevate's different15A. Yes.16than Apogee and Perigee® and Avaulta®. So I16Q. And have you been critical of17do review them from time to time.17the design of the material?18Q. And did you say you have not18A. Yes.	24	Q. Did you read the Prolift® IFU	24	what kind of product is that?
1 when you used it that one time? 2 A. I did. 3 Q. Had you read it since until you 4 became involved in this litigation? 4 D. Okay. What kind of sling? 5 A. I read it again. 6 Q. When you became that's what 7 you mean. 7 Q. Okay. Different from retropubic? 8 A. It's in front. 9 Q. But the gap of years, you 9 Well, let me ask you this: On both of those products, have you been critical of the instrumentation? 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to than Apogee and Perigee® and Avaulta®. So I 16 do review them from time to time. 18 Q. And did you say you have not 1 A. That's a sling. 2 Q. Okay. What kind of sling? 4 A. Prepubic. 6 A. Ir's in front. 7 Q. Okay. And what's the problem with it? 9 Well, let me ask you this: On both of those products, have you been critical of the instrumentation? 11 A. That's a sling. 2 Q. Okay. What kind of sling? 4 Q. Okay. Different from retropubic? 4 Q. Okay. Different from retropubic? 4 A. It's in front. 9 Well, let me ask you this: On both of those products, have you been critical of the instrumentation? 12 A. Yes. 13 Q. Have you been critical of the technique described in the IFU? 15 A. Yes. 16 Q. And have you been critical of the design of the material? 17 the design of the material? 18 A. Yes.		Page 247		Page 249
A. I did. Q. Had you read it since until you became involved in this litigation? A. I read it again. Q. When you became that's what you mean. A. Yes. Q. But the gap of years, you hadn't read it in between? A. I looked at it from time to critical of the instrumentation? A. I read a lot of IFUs. As I mentioned have to study them on how they're designed to have to study them on how they're designed to than Apogee and Perigee® and Avaulta®. So I do review them from time to time. Q. Okay. What kind of sling? A. Prepubic. Q. Okay. Different from retropubic? A. It's in front. Q. Okay. And what's the problem with it? Well, let me ask you this: On both of those products, have you been critical of the instrumentation? A. Yes. Q. Have you been critical of the technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes. A. Yes.	1		1	
Q. Had you read it since until you became involved in this litigation? A. I read it again. Q. Okay. Different from retropubic? A. It's in front. Q. Okay. And what's the problem A. Yes. Q. Okay. And what's the problem Well, let me ask you this: On both of those products, have you been In time. I read a lot of IFUs. As I mentioned acarlier, I own all of the products because I have to study them on how they're designed to be able to remove them. Elevate's different be able to remove them. Elevate's different do review them from time to time. Q. Okay. And what's the problem Well, let me ask you this: On both of those products, have you been critical of the instrumentation? A. Yes. Q. Have you been critical of the technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.		•		
4 became involved in this litigation? 5 A. I read it again. 6 Q. When you became that's what 7 you mean. 8 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 than Apogee and Perigee® and Avaulta®. So I 16 do review them from time to time. 17 Q. Okay. Different from retropubic? 4 Q. Okay. Different from retropubic? 5 A. It's in front. 7 Q. Okay. And what's the problem with it? 9 Well, let me ask you this: On both of those products, have you been critical of the instrumentation? 11 A. Yes. 12 Q. Have you been critical of the technique described in the IFU? 13 A. Yes. 14 A. Yes. 15 Q. And have you been critical of the design of the material? 16 the design of the material? 17 the design of the material? 18 Q. And did you say you have not 18 A. Yes.				
5 A. I read it again. 6 Q. When you became that's what 7 you mean. 8 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 16 Tretropubic? A. It's in front. Q. Okay. And what's the problem with it? Well, let me ask you this: On both of those products, have you been critical of the instrumentation? A. Yes. Q. Have you been critical of the technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.				
Q. When you became that's what you mean. A. Yes. Q. Okay. And what's the problem with it? Q. But the gap of years, you hadn't read it in between? A. I looked at it from time to I lowed at it from time to I read a lot of IFUs. As I mentioned A. Yes. A. Yes. A. Yes. A. I looked at it from time to I critical of the instrumentation? A. Yes.				
you mean. A. Yes. Q. Okay. And what's the problem with it? Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 7 Q. Okay. And what's the problem with it? 9 Well, let me ask you this: On both of those products, have you been critical of the instrumentation? 11 A. Yes. Q. Have you been critical of the technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.		——————————————————————————————————————		-
8 A. Yes. 9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 8 with it? 9 Well, let me ask you this: On both of those products, have you been 10 critical of the instrumentation? 11 A. Yes. 12 Q. Have you been critical of the technique described in the IFU? 13 A. Yes. 14 Q. And have you been critical of the design of the material? 15 A. Yes. 16 A. Yes.	-	•		
9 Q. But the gap of years, you 10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 19 Well, let me ask you this: On 10 both of those products, have you been 11 critical of the instrumentation? 12 A. Yes. 13 Q. Have you been critical of the technique described in the IFU? 15 A. Yes. 16 Q. And have you been critical of the design of the material? 17 the design of the material? 18 A. Yes.	_			- •
10 hadn't read it in between? 11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 10 both of those products, have you been critical of the instrumentation? 12 A. Yes. 13 Q. Have you been critical of technique described in the IFU? 14 A. Yes. 15 Q. And have you been critical of the design of the material? 16 A. Yes.				
11 A. I looked at it from time to 12 time. I read a lot of IFUs. As I mentioned 13 earlier, I own all of the products because I 14 have to study them on how they're designed to 15 be able to remove them. Elevate's different 16 than Apogee and Perigee® and Avaulta®. So I 17 do review them from time to time. 18 Q. And did you say you have not 11 critical of the instrumentation? A. Yes. Q. Have you been critical of technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.		- · · · · · · · · · · · · · · · · · · ·		
time. I read a lot of IFUs. As I mentioned a earlier, I own all of the products because I be able to remove them. Elevate's different than Apogee and Perigee® and Avaulta®. So I do review them from time to time. Q. Have you been critical of the technique described in the IFU? A. Yes. A. Yes. Q. Have you been critical of the technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.				*
earlier, I own all of the products because I have to study them on how they're designed to be able to remove them. Elevate's different than Apogee and Perigee® and Avaulta®. So I do review them from time to time. Q. Have you been critical of technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.				
have to study them on how they're designed to be able to remove them. Elevate's different than Apogee and Perigee® and Avaulta®. So I do review them from time to time. Q. And did you say you have not 14 technique described in the IFU? A. Yes. Q. And have you been critical of the design of the material? A. Yes.				
be able to remove them. Elevate's different than Apogee and Perigee® and Avaulta®. So I than Apogee and Perigee® and Avaulta®. So I than Apogee and Perigee® and Avaulta®. So I the design of the material? Q. And did you say you have not the design of the material? A. Yes. A. Yes.				
than Apogee and Perigee® and Avaulta®. So I Q. And have you been critical of do review them from time to time. 17 the design of the material? A. Yes.		· · · · · · · · · · · · · · · · · · ·		•
17 do review them from time to time. 18 Q. And did you say you have not 19 the design of the material? 18 A. Yes.				
18 Q. And did you say you have not 18 A. Yes.		* *		
		served as an expert witness against any other		Q. Okay. And you don't believe
		÷ *		
1		•		
23 Q. Okay. Have you? 23 Q. Okay. 24 I'll ask you again. 24 A. And they're not on the market.				- •
T ZE THASK VOILAGAIN T ZE A A HOLDEV TE HOLON THE MARKET	24	I'll ask you again.	4	A. And they're not on the market.

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	Page 250		Page 252
1	Q. Okay.	1	Q. Okay. Did any doctors at your
2	A. They're gone.	2	hospital ever use Gynemesh® PS for prolapse
3	Q. So is there any sling product	3	repair?
4	in the world that polypropylene sling	4	A. I don't think so.
5	product in the world that you believe is safe	5	MR. BALL: Okay. Why don't we
6	in all aspects: Instrumentation, technique,	6	take a break. I think I'm about
7	and material?	7	finished here. I've got to regroup a
8	A. No.	8	little bit here.
9	Q. Is there any polypropylene	9	(Off the record at 1:32 p.m.)
10	sling product in the world that you believe	10	QUESTIONS BY MR. BALL:
11	is reasonably safe with respect to the	11	Q. Doctor, would an experienced
12	material, the mesh material?	12	surgeon before 2005 performing prolapse
13	A. No.	13	surgery with Gynemesh® PS know that pain with
14	Q. Okay. When do you do an ASC?	14	intercourse was a possible complication?
15	Under what circumstances?	15	A. Yes.
16	A. So I'll perform an ASC on a	16	Q. Would an experienced surgeon
17	patient that is a younger woman, someone that	17	before 2010 using Gynemesh® PS for prolapse
18	has a shortened vagina, someone that has	18	know that vaginal scarring was a possible
19	Q. These are alternatives, or they	19	complication?
20	have to have all of these things?	20	A. Yes.
21	A. No, it's either	21	Q. Would they know that infection
22	Q. This or that?	22	was a possible complication?
23	A. This or that.	23	A. Yes.
24	Q. Okay.	24	Q. Would they know that urinary
_	Page 251		Page 253
1	A. Someone who has a job that	1	frequency, urgency, dysuria, retention,
2	requires heavy lifting. Someone that has	2	obstruction and incontinence were possible
3	asthma or bronchitis. Just a more durable	3	complications?
4 5	repair. She needs a more durable repair.	4	A. If we could break that question
5 6	Q. Was it within the standard of	5	up again.
7	care up until 2012 for a surgeon to use	6	Q. Yeah.
	Gynemesh® PS products in repair of prolapse?	7	Would an experienced surgeon
8	A. Would you ask the question	8	before 2010 know that urinary frequency would
9 10	again?	9	be a possible complication after prolapse surgery with Gynemesh® PS?
11	Q. Yeah.Was it within the standard of	10	A. No.
12	care, the acceptable standard of care, for a	12	
13	surgeon to use a Gynemesh® PS product for	13	Q. What about urgency?A. No.
13	prolapse repair up through 2012?	14	
15	A. Yes.	15	Q. What about dysuria?A. No.
16	Q. Was it within the standard of	16	Q. What about retention?
	care for doctors to use TVT® for SUI, even	17	A. No.
17			Q. So is retention a recognized
17 18	today?	1 7 2	
18	today?	18	
18 19	A. Yes.	19	problem with Gynemesh® PS used for prolapse
18 19 20	A. Yes.Q. Okay. Did any doctor at your	19 20	problem with Gynemesh® PS used for prolapse surgery?
18 19 20 21	A. Yes. Q. Okay. Did any doctor at your hospital ever use TVT®?	19 20 21	problem with Gynemesh® PS used for prolapse surgery? A. Depends on how tight you make
18 19 20 21 22	A. Yes. Q. Okay. Did any doctor at your hospital ever use TVT®? A. Yes.	19 20 21 22	problem with Gynemesh® PS used for prolapse surgery? A. Depends on how tight you make it.
18 19 20 21	A. Yes. Q. Okay. Did any doctor at your hospital ever use TVT®?	19 20 21	problem with Gynemesh® PS used for prolapse surgery? A. Depends on how tight you make

64 (Pages 250 to 253)

Page 254 Page 256 1 And that wouldn't have been 1 thinking about it as a surgeon is I'm going 2 known as a possible complication before 2010? 2 to get scarring from just doing surgery, and 3 3 I think I answered, yes, that there is No. A. 4 4 Why do you say that? scarring from doing that. O. 5 A. I don't think anyone knew 5 But if you're asking the 6 6 exactly what would happen when you put mesh question is the scarring the same when 7 7 in there. putting in the mesh, then the answer is no. 8 8 Q. Was incontinence a potential O. No, that's not what I'm asking. 9 9 A. complication? Okav. 10 10 They know they're going to A. Yes. Q. 11 O. That was known before 2010? 11 create a scar by putting in mesh, right? 12 A. Yes. 12 A. They know they're going to 13 Q. Okay. Organ nerve damage, was 13 create a scar by doing surgery. 14 that a potential complication that was known 14 Q. And they know that they're 15 to experienced surgeons using Gynemesh® PS 15 going to create -- well, won't there be 16 before 2010? 16 scarring connected with the implantation of 17 A. Yes. 17 the mesh, right? 18 But it's a different kind of 18 A. Yes. 19 nerve damage than -- they would know about it 19 Q. And wouldn't every experienced 20 because they have to open the vaginal wall 20 surgeon before 2010 know that there will be 21 21 some contraction connected with the scarring 22 What they didn't know was the 22 of the mesh surgery? 23 consequence that would happen, you know, 23 A. No. I didn't know. I didn't 24 they're cutting the vagina, they're opening 24 know. Page 255 Page 257 1 it up and we talk about nerve damage, did Q. Before 2010, would an 2 they know about it. 2 experienced surgeon -- so you're saying at no 3 3 time versus before 2010 would an experienced So, yes, they would know about 4 it because they're doing surgery. But what 4 surgeon know that there would be the 5 5 they wouldn't know about is the fact that potential for contraction connected with mesh 6 they're going to put an implant in her that's 6 surgery? 7 then going to constrict and change 7 A. I'm answering that question 8 8 everything. honestly on what I knew. I don't know what 9 Q. Would an experienced surgeon 9 other people knew so I'm answering that 10 before 2010 using Gynemesh® -- in and before 10 question based on what I knew. I was 11 2010 using Gynemesh® PS for prolapse know 11 surprised the first time that I had a patient 12 that there was a potential of contraction? 12 that had a contraction like that. 13 13 Q. And that was 2010, after 2010? A. 14 Would they know that there was 14 I'm not sure exactly when, but Q. a potential of scar formation? 15 15 around that time frame. When the literature 16 A. Not the kind of scar we're 16 started talking about contraction and mesh 17 talking about. 17 exposure and et cetera, it all made sense. 18 Q. I'm not talking about degrees. 18 Q. Would the average surgeon in 19 Would they know that there 19 2010 and before know that there was a 20 would be some degree of contraction from 20 potential of erosion or exposure from mesh, 21 scarring with the use of Gynemesh® PS, would 21 from Gynemesh®, used in prolapse? 22 an experienced surgeon know that before 2010? 22 A. 23 A. I'm not sure I know how to 23 And would the average surgeon 24 answer the question. Because the way I'm 24 in 2010 or before know that there was a

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	Page 258		Page 260
1	potential for another surgery after the use	1	Q. The potential for a chronic
2	of the mesh for prolapse?	2	foreign body response?
3	A. Probably not.	3	A. No.
4	Q. Would they know there was the	4	Q. The potential for a failure of
5	possibility that some mesh might have to be	5	the procedure to cure the SUI?
6	removed?	6	A. Yes.
7	A. I think what they no, what	7	Q. The potential for an additional
8	they knew is that they were going to apply	8	surgery?
9	silver nitrate in the office and put some	9	A. Yes.
10	estrogen on it and that would take care of	10	Q. The potential for some of the
11	it, and it didn't.	11	mesh to be removed?
12	Q. So you don't think the average	12	A. No.
13	surgeon knew that a possible complication of	13	Q. And the potential of
14	using Gynemesh® for prolapse was that there	14	contraction of the TVT®?
15	might need to be surgery to remove some of	15	A. No.
16	the mesh?	16	Q. When do you think that doctors
17	A. No.	17	became aware of the problems that you've
18	Q. Did the average surgeon in 2010	18	described for us today?
19	or before know that if they used Gynemesh®	19	When did the medical community
20	for prolapse there might be a recurrent	20	become aware of the problems that you've
21	prolapse?	21	described about TVT® and Gynemesh®?
22	A. No.	22	A. After 2011.
23	Q. They thought it was going to be	23	Q. Okay. And what happened in
24	100 percent successful?	24	2011?
	100 percent baccesstat.		2011.
	Page 259		Page 261
1	A. Oh, they thought it was going	1	A. Well, there was the initial FDA
2	to be fantastic.	2	announcement that that some of these things
3	Q. 100 percent?	3	might be rare, and then in 2011 when it
4	A. Close to it. 100 percent	4	wasn't rare, and it all just kind of blew up.
5	doesn't exist in clinical medicine, but	5	Q. You said there was the initial
6	Q. Well, I asked did they know	6	announcement.
7	that a potential complication was that there	7	When was that?
8	would be a recurrent prolapse?	8	A. I believe it was 2008.
9	A. I don't think they did, no.	9	Q. Right.
10	Q. Okay. Did the average surgeon	10	So wasn't there general
11	in 2010 or before know that the there was	11	knowledge in the medical community in 2008 of
12	a potential for a long-term foreign body	12	these problems that I just listed?
13	response from the mesh?	13	A. To some degree, but it wasn't
14	A. Absolutely not.	14	really an awareness. I didn't I'm
15	Q. Did the average surgeon in 2010	15	answering the question honestly based on what
16	or before who implanted TVT® know that there	16	I knew because that's what I know. I'm not
17	was a potential for pain with intercourse?	17	sure what other people knew. Maybe there
18	A. No.	18	were some that are more alert and smarter
19	Q. Did that person know that there	19	than me out there, but I didn't know the
20	was the potential for vaginal scarring?	20	extent that all of these problems would exist
21	A. No.	21	until after 2011 and especially 2012.
22	Q. The potential for erosion or	22	I would see patients, and I
23	exposure?	23	didn't think it was the mesh either. I
24	A. Probably, yes.	24	didn't really know what to tell them until
	71. 1100a01y, yes.		Giant roung know what to ton thom until
		1	

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	Page 262		Page 264
1	all of these announcements happened.	1	be affected by secondary gain?
2	Q. Your referrals for explants,	2	A. I'm sure there are, which is
3	where do they come from?	3	why when patients show up, if I can't find
4	A. They are global.	4	more than one reason and I just submitted
5	Q. Let me ask you this, a simpler	5	an abstract to the AUGS; it's not accepted
6	question.	6	yet very few patients present with a
7	Do any of your referrals for	7	single symptom that I've operated on. They
8	explants come from lawyers, where the	8	usually have pain, erosion, failure of the
9	patients were referred by lawyers to you?	9	device.
10	A. So the short answer is yes	10	So it's I'm not I don't
11	because these patients ask their lawyers	11	know if you're implying, maybe you're not,
12		12	but I'm going to answer the question. I'm
13	where can I get help. So at least in	13	
13 14	St. Louis I am one of the people that can fix	14	not looking to remove the mesh when there's
	this. My referrals come from other doctors,	15	no problem. I put it in. So if it's working
15	other patients, other surgeons, that put in		fine, and I think it's in the best interests
16	mesh, urologists, gynecologists, internal	16	of the patient to leave it alone, I leave it
17	medicine doctors.	17	alone.
18	Q. And lawyers?	18	But there's a large number of
19	A. Yeah.	19	patients that truly have problems that don't
20	Q. Okay. Do you know what	20	know where to get help. There was a paper by
21	percentage of your referral practice comes	21	I think Shakain and Posen that said many
22	from people involved in litigation?	22	years ago that there ought to be referral
23	A. It's a very small percentage.	23	centers.
24	2 percent.	24	Q. Shakitan and Kosan?
	Page 263		Dama 265
	rage 203		Page 265
1		1	
1 2	Q. Do you ask every one of your	1 2	
			A. Is that how you say his name?
2	Q. Do you ask every one of your explant patients whether they're involved in	2	A. Is that how you say his name? Okay. There's a bunch of
2	Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not.	2 3	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their
2 3 4	 Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis 	2 3 4	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I
2 3 4 5	 Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? 	2 3 4 5	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that.
2 3 4 5 6	 Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? A. They fill out a little piece of 	2 3 4 5 6 7	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these
2 3 4 5 6 7	 Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? A. They fill out a little piece of paper. 	2 3 4 5 6	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these women can have help.
2 3 4 5 6 7 8	 Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? A. They fill out a little piece of paper. 	2 3 4 5 6 7 8	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these women can have help. So that, to me, was the first
2 3 4 5 6 7 8 9	Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? A. They fill out a little piece of paper. Q. About referral?	2 3 4 5 6 7 8	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these women can have help.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you ask every one of your explant patients whether they're involved in a lawsuit? A. I do not. Q. So how do you have any basis for knowing that? A. They fill out a little piece of paper. Q. About referral? A. About referral, and it says "Attorney." Q. Okay. So my question I appreciate that. My question is a little bit different. I'm not talking about people who are directly referred. I'm asking about what percentage of your patients are involved in a lawsuit. A. I don't know. I don't ask. It's really none of my business. Q. And you don't ask?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Is that how you say his name? Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these women can have help. So that, to me, was the first time that someone recognized that these women have legitimate problems, and there is nothing anywhere to help guide care for them. Q. Tell me about the paper you submitted to AUGS. A. It's an abstract. Q. An abstract. A. An abstract. Q. And was it based on a study, or what's it about? A. All it's doing so far I think it after going through this and

	Page 266		Page 268
1	slings and how many are prolapse kits.	1	related to any kind of vaginal surgery from
2	That's all it really was looking at, but I'm	2	any manufacturer that gives percentages of
3	going to reconsider that.	3	complications?
4	So the vast majority are	4	A. Unfortunately, none do.
5	slings.	5	Q. Okay. So these photographs
6	Q. The vast and you told us	6	that are in your Gynemesh® report, which is
7	that earlier in the deposition.	7	Exhibit 3, what is the significance of those
8	A. Okay.	8	photographs?
9	Q. The vast majority of your	9	They're at page 7, et cetera.
10	explant procedures are slings?	10	7 and 8.
11	A. Yes, sir.	11	A. So it shows the bunching, the
12	Q. Of various manufacturers?	12	rolling, the cording, the excessive
13	A. Yes.	13	scarification of the mesh once it's placed.
14	And it's not mentioned who they	14	It doesn't
15	are in the paper.	15	Q. So let's take the photograph on
16	Q. And you don't know enough about	16	page 8.
17	market share and everything to determine	17	Tell me what that's showing,
18	whether the TVT® is overrepresented in your	18	photographs.
19	practice or not?	19	A. I have page 7, want me to go to
20	A. No, but I'm going to see if I	20	page 8?
21	can learn.	21	Q. Yeah.
22	Q. Would you say that a warning is	22	A. So it's showing a section of
23	adequate if it gives a doctor sufficient	23	Gynemesh® that's been explanted. It's been
24	information to counsel patients and make a	24	cut in the middle and where the surgeon cut
	Page 267		Page 269
1	surgical decision?	1	it in a square, it has folded and corded near
2	A. Would you repeat that?	2	the lateral edges.
3	Q. Yeah.	3	Q. Okay. And maybe we will use
4	Would you say a warning is	4	Jim's color ones.
5	adequate if it gives the doctor sufficient	5	Show me what you're talking
6	information to counsel patients and make a	6	about.
7	surgical decision?	7	A. See how it's folded and rolled
8	A. If it gives adequate	8	right there? Are we looking at the right
9	information?	9	one?
10	Q. No, gives sufficient	10	Q. Yeah. Well, I'm not seeing any
11	information is what I meant to say.	11	folding.
12	You said in here sometimes the	12	So that's the mesh folding and
13	warnings are inadequate?	13	rolling on the top picture on page 8?
14	A. Yes.	14	A. Yes. And it can't been seen
15	Q. You've said that. So I'm	15	easily because it's encased in scar tissue
16	trying to get your definition of what	16	and tissue. It's not a single flat layer.
17	inadequate is. Maybe I'll just ask that.	17	Q. I can't tell that, but if I'm
18	What's your definition of an	18	assuming
19	adequate warning?	19	A. Compare it to the picture below
	A. Percentages, how often does it	20	it.
20	la americana e e esta a tila a la a a a e e a mitere	21	Q. Okay. Which is what?
21	happen, what's the severity.		
21 22	Q. Of complications?	22	A. It's another it's the piece
21	• • • • • • • • • • • • • • • • • • • •		

68 (Pages 266 to 269)

	Page 270		Page 272
1	flat and the edge here is rolled?	1	A. I didn't do a calculation on
2	Q. I'm not being difficult. I	2	the percentage, no.
3	don't see it, but I wanted to hear what you	3	Q. How would Ethicon be able to
4	had to say about it so I've heard that.	4	determine the percentage of complications?
5	I appreciate it.	5	You said a warning to be
6	A. Okay.	6	adequate needed to give the percentage of the
7	Q. You say on page 10	7	potential complications such as erosion and
8	A. If I could interrupt for a	8	nerve damage and
9	second, a better page to represent the	9	A. Yes.
10	folding is on page 7.	10	Q contraction, et cetera.
11	Q. Okay.	11	How would Ethicon determine the
12	A. On this one, maybe you can see	12	percentages to put in an IFU?
13	it a little bit better, it's a lot thicker.	13	A. What they would have had to do
14	See, it's thicker?	14	when all of this when these products
15	Can you see the edges?	15	started is very similar to what's given to a
16	Q. I see it's thicker. I guess	16	patient that has a pacemaker, a card. Each
17	that just meant more tissue came with it.	17	of those cards is registered with the company
18	A. No. My technique is such that	18	so the company knows how many implants went
19	it scrapes it off and it's folded.	19	in. That patient carries that card and if
20	I'm sure I have the picture	20	there's a complication, the patient calls a
21	laterally head-on.	21	number to report these complications and then
22	Q. So what you're saying in all of	22	the patient is seen by a doctor to confirm
23	these photographs what we're seeing is almost	23	that.
24	totally mesh, not tissue?	24	Q. Well, that process would have
	totally most, not dispate.		Q. Wen, that process would have
	D 081		
	Page 271		Page 273
1	A. Yes.	1	Page 273 taken years in order to get reliable
1 2		1 2	
	A. Yes.		taken years in order to get reliable
2	A. Yes.Q. Okay. That might have been my	2	taken years in order to get reliable percentages of complications, true?
2	A. Yes. Q. Okay. That might have been my misunderstanding.	2 3	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should
2 3 4	A. Yes.Q. Okay. That might have been my misunderstanding.A. Yes.	2 3 4	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should have done a project like that prior to
2 3 4 5	 A. Yes. Q. Okay. That might have been my misunderstanding. A. Yes. Q. So if they're thicker, if the 	2 3 4 5	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should have done a project like that prior to releasing it to the average surgeon.
2 3 4 5 6	 A. Yes. Q. Okay. That might have been my misunderstanding. A. Yes. Q. So if they're thicker, if the piece is thicker in the photograph, it's 	2 3 4 5 6	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should have done a project like that prior to releasing it to the average surgeon. Q. So how many patients would have had to have Prolift® put in at the clinical trial stage before the product went on the
2 3 4 5 6 7	 A. Yes. Q. Okay. That might have been my misunderstanding. A. Yes. Q. So if they're thicker, if the piece is thicker in the photograph, it's thicker because the mesh has rolled over is 	2 3 4 5 6 7	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should have done a project like that prior to releasing it to the average surgeon. Q. So how many patients would have had to have Prolift® put in at the clinical
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Okay. That might have been my misunderstanding. A. Yes. Q. So if they're thicker, if the piece is thicker in the photograph, it's thicker because the mesh has rolled over is what you're saying; not thicker because it happens to have more tissue connected with it? A. Correct. If I did that, I would be removing the woman's rectum and bladder. Q. Go to page 10 of your Gynemesh® report, it says in the middle of the page, "The Gynemesh® PS contains pore sizes much smaller than the necessary 1 millimeter." A. Yes. Q. This gets to the variable pore size you were talking about before? A. Yes. Q. Do you know what percentage of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	taken years in order to get reliable percentages of complications, true? A. Yes, but the company should have done a project like that prior to releasing it to the average surgeon. Q. So how many patients would have had to have Prolift® put in at the clinical trial stage before the product went on the market in order to get reliable percentages of complications in your view? A. 500. Q. Other than pacemakers, do you know of any other product that used the kind of procedure you just described? A. Yes. I believe you mentioned your daughter works in the ICU. So when someone comes in with a neurovascular injury and needs a coil, those patients get a little card that lets them know that they have coils in, et cetera, stents, filters. Q. Is the Gynemesh® PS any more

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	Page 274		Page 276
1	more stiff than others.	1	study reach that conclusion?
2	Q. But I think your view is	2	A. Yes.
3	they're all too stiff and inflexible?	3	Q. Okay. They reached that same
4	A. Yes.	4	conclusion?
5	Q. Okay. Now, back to our report	5	A. Yes.
6	on the clinical reports at pages 21 and	6	There were serious adverse
7	22, those are footnoted at footnotes 34, kind	7	events. They had to distinguish between
8	of like through 30 through 39 of your	8	transvaginal mesh and what was Prolift®. So
9	report, right?	9	they didn't even met their success rate.
10	A. Yes.	10	Even though they had a success rate of
11	Q. Do you believe that you gave a	11	20 percent, they were, I believe, 18.5, they
12	fair and balanced representation of the	12	were really close to not being as successful
13	findings of those reports?	13	as they wanted.
14	A. I do.	14	Q. Well, you quoted a number of
15	Q. Okay. Now, did those reports	15	pieces of data in here.
16	have conclusions in them?	16	Why did you not quote the
17	A. Some did, yes.	17	specific conclusion from the people that did
18	Q. Okay. Did you cite the	18	the study?
19	conclusions in your report?	19	A. I thought I summarized it to
20	A. I didn't cite the exact	20	the best of my ability everything that was
21	conclusion. What I do is I review everything	21	available to me. There's so many reports, so
22	that's available, and I abstract the	22	
23	information and	23	many papers
24		24	Q. I'm talking about these reports
24	Q. So did the people that prepared	24	that you quoted specifically.
	Page 275		Page 277
1	those reports you've written in here that	1	Why did you not quote the
2	the study demonstrated that the mesh was not	2	conclusion of the report?
3	an effective prolapse treatment and presented	3	You quoted the data, but you
4	unreasonable risks?	4	didn't quote the conclusion.
5	A. Yes.	5	Why is that?
6	Q. Was that the conclusion of the	6	A. At the time I thought that was
7	study?	7	the most important piece of information that
8	A. On the conclusion by Karram,	8	I placed in the report.
9	Maher on posterior vaginal wall prolapse,	9	Q. When you're giving your
10	absolutely.	10	opinions as to whether the IFU adequately
11	Q. No, I'm saying the conclusion	11	for the Gynemesh® PS and TVT® provides an
12	of the study that's referenced at footnote	12	adequate warning of the risks and
13	34.	13	complications, are you basing that on your
14	A. So I was looking at the wrong	14	own opinions and experience?
15	one. So footnote 34	15	A. I'm basing it on the totality
16	Q. Footnote 34 is the clinical	16	of everything that was known from the
17	study report.	17	internal documents at Ethicon, all the
18	A. Yes.	18	material that was available to me, and
19	Q. And you cite data from the	19	knowing what's in the IFU, knowing what the
20	clinical study report, and you say your	20	company knew that they didn't include and my
21	conclusion was that the mesh was not	21	own experience.
22	effective prolapse treatment and presented	22	Q. Is there any objective standard
23	unreasonable risks.	23	that you are applying in determining whether
24	Did the people who did this	24	the warnings were adequate?

	Page 278		Page 280
1	A. Yes.	1	Q. Okay. Now, all of the
2	Q. What's the objective standard?	2	materials that you reviewed in this matter
3	A. If, for example, it's mentioned	3	were sent to you by the lawyers for the
4	repeatedly in the internal documents for a	4	plaintiffs?
5	very long time that there's a problem with	5	A. Yes.
6	the product, and they're not including it,	6	Q. Okay.
7	that's not a fair representation of	7	A. 52 discs.
8	truthfulness of what's wrong with the product	8	MR. BALL: And they're all in
9	or not.	9	the CD, all 52 of them; is that right?
10		10	MR. MATTHEWS: It's what my
11	Q. What's the objective standard	11	· · · · · · · · · · · · · · · · · · ·
12	you're applying in reaching that conclusion? A. I'm not sure I understand the	12	paralegal says. I promise I have
			not looked at it to verify that.
13	question then.	13	QUESTIONS BY MR. BALL:
14	Q. Well, then sometimes they're	14	Q. Did you ask the lawyers whether
15	like FDA regulations, there's industry	15	there were any other documents or depositions
16	standards.	16	other than what they gave you?
17	Is there any kind of standard	17	A. I don't think I did.
18	you can point to and say, "This is the	18	Q. And did you do any research of
19	standard that should have been applied to the	19	your own into the medical literature
20	warning," and they didn't meet it?	20	independent from the medical papers they gave
21	A. Yeah, Ethicon's own where it	21	you?
22	says our credo is to take care of our	22	A. Yes, I did.
23	doctors, our nurses and our patients. They	23	Q. And how did you do that?
24	had an obligation if they knew that these	24	A. I subscribe to I'm a member
	Page 279		Page 281
1	Page 279	1	Page 281
1	meshes had biodegradable components and they	1	of the International Gynecologists
2	meshes had biodegradable components and they knew it, and they have a credo that says	2	of the International Gynecologists Association, so I went on the website and I
2	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our	2 3	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal,
2 3 4	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in,	2 3 4	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I
2 3 4 5	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in, I think that's a very objective way of saying	2 3 4 5	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I did the same for the American Journal of
2 3 4 5 6	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in, I think that's a very objective way of saying they knew about it, and they didn't disclose	2 3 4 5 6	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I did the same for the American Journal of OB/GYN. I did the same for Obstetrics and
2 3 4 5 6 7	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in, I think that's a very objective way of saying they knew about it, and they didn't disclose it.	2 3 4 5 6 7	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I did the same for the American Journal of OB/GYN. I did the same for Obstetrics and Gynecology. And then I asked my librarian to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in, I think that's a very objective way of saying they knew about it, and they didn't disclose it. Q. You do not rely upon internal company documents in making decisions for your patients, true? A. I don't get no, I don't have internal document access. Q. Right. And other than the Boston Scientific products you've mentioned, other than the two Ethicon products here, are there any other products you've been engaged upon to testify about? A. I've been deposed as an expert on those two products we've talked about. Q. Plus the two today?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I did the same for the American Journal of OB/GYN. I did the same for Obstetrics and Gynecology. And then I asked my librarian to do a search, and I asked her to do a search for "Gynemesh®" and "TVT®." Q. Okay. Did you come up with any papers that were different or additional to what the lawyers had given you? A. There were some different ones, but when I looked at them, I didn't really think that they added either had bias, they were either employees of Ethicon, or they were the studies were funded by Ethicon or there were weaknesses in the methodology so I didn't use them. Q. So your opinion that there is no reasonably safe mesh product for SUI, would you agree that there's a large body of published peer-reviewed literature that runs
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	Page 282		Page 284
1	A. I do.	1	reliable?
2	Q. Okay.	2	A. They have bias to them.
3	A. But here's what else I know:	3	Q. I didn't ask that.
4	Everyone understands, clinicians, doctors,	4	Are they automatically not
5	companies, that we need lightweight,	5	reliable?
6	macroporous mesh. And they've done wonders	6	A. Sometimes, yes.
7	to try to conduct research on that. There is	7	Q. All of them?
8	a paper by Mowali that even says that the	8	A. I wouldn't say all of them.
9	current Gynemesh® PS when placed in rhesus	9	Q. There's a lot of good
10	monkeys not only doesn't help, it's	10	scientific data that's produced by studies
11	detrimental to the vagina of a rhesus monkey,	11	funded by companies, true?
12	which is probably the best paper out there	12	A. Some.
13	because it's not a pig, it's not a cow, it's	13	Q. Would you agree that your
14	not skid. It's the closest to the human	14	opinion that there is no safe TVT® strike
15	vaginal tissue as possible. Not only does it	15	that.
16	not help, it's detrimental. Every aspect of	16	Would you agree that your
17	healing is impaired by Gynemesh® PS.	17	opinion that TVT® was so unsafe it never
18	So everyone knows that we need	18	should have been on the market is not
19	lighter weight meshes, and yet every single	19	generally accepted in the scientific medical
20	company, including Ethicon, continues to use	20	community? You agree with that?
21	a sling that's 100 grams per meter squared.	21	A. Yes.
22	MR. BALL: Okay. I'll just	22	Q. Okay. So did you automatically
23	have to move to strike everything	23	not consider any study that had any funding
24	after the words "I do."	24	from Ethicon?
	Page 283		Page 285
1	QUESTIONS BY MR. BALL:	1	
		+	A. I considered it.
2	Q. Would you agree that the	2	A. I considered it.Q. Did you automatically not cite
3			
	Q. Would you agree that the	2	Q. Did you automatically not cite
3	Q. Would you agree that the general scientific consensus is not in line	2	Q. Did you automatically not cite in your report any study if it had funding
3 4	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably	2 3 4	Q. Did you automatically not cite in your report any study if it had funding from Ethicon?
3 4 5	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI?	2 3 4 5	Q. Did you automatically not cite in your report any study if it had funding from Ethicon? A. No.
3 4 5 6	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI? A. No.	2 3 4 5 6	Q. Did you automatically not citein your report any study if it had fundingfrom Ethicon?A. No.Q. You didn't cite it?
3 4 5 6 7	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI? A. No. Q. That's not the general	2 3 4 5 6 7	 Q. Did you automatically not cite in your report any study if it had funding from Ethicon? A. No. Q. You didn't cite it? A. No, and that's not the question
3 4 5 6 7 8	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI? A. No. Q. That's not the general consensus, true? A. I don't think it's a general consensus.	2 3 4 5 6 7 8	 Q. Did you automatically not cite in your report any study if it had funding from Ethicon? A. No. Q. You didn't cite it? A. No, and that's not the question I'm answering.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI? A. No. Q. That's not the general consensus, true? A. I don't think it's a general consensus. Q. Okay. Thank you. Can you tell me if you saw studies and decided not cite them in your reports, can you tell me what criteria you used to what was cited in the report and what wasn't? A. Number of patients, follow-up, if the report was done by someone that I identified in my reading as an employee of Ethicon or if the study was funded by Ethicon. Those have a lot of bias to them. Q. Well, are you saying that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Did you automatically not cite in your report any study if it had funding from Ethicon? A. No. Q. You didn't cite it? A. No, and that's not the question I'm answering. Q. I am sorry. You still would include it in your report although it might have been funded by Ethicon? A. If I thought it had merit, I would have. Q. Okay. And so you're saying any of the you remember we went through some long-term studies with respect to both Gynemesh® PS products and TVT®. Do you remember that? A. Yes. Q. And you didn't cite any of those in your report?

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	Page 286		Page 288
1	Q. Let me finish the question.	1	valid study?
2	A. Okay.	2	A. It was not a good study,
3	Q. You did not cite any studies	3	correct.
4	giving long-term results on either Gynemesh®	4	Q. Okay. And those studies were
5	PS products or TVT®, true?	5	all peer-reviewed, and some of them were
6	A. Correct.	6	published in esteemed journals, true?
7	Q. Okay. And are you saying that	7	A. They're peer-reviewed.
8	none of those were reliable studies?	8	Q. What do you consider to be the
9	A. When I assess them, I did not	9	kind of first tier journals in your field?
10	think that they had the merit that I wanted	10	A. The ones I looked at,
11	to use them in my report.	11	Obstetrics and Gynecology, the American
12	Q. And what was your basis for	12	Journal of OB/GYN, International
13	that?	13	Urogynecology Journal, Journal of Urology.
14	What was non-meritorious about	14	Q. What about the New England
15	them?	15	Journal of Medicine?
16	A. I can't remember the specifics	16	A. Oh, yes.
17	of each report, but it had to do with either	17	Q. Any others? I just thought of
18	follow-up, for example, the Nilsson 17-year	18	that one.
19	study. I mean, I could do the calculations,	19	A. Yeah, it's a good one.
20	but the percentages are off, and half those	20	I think I have that one in
21	patients were lost to follow-up. So you	21	there, don't I?
22	can't know whether the other half are doing	22	Q. How about JAMA?
23	well or not doing well.	23	A. JAMA doesn't really have a lot
24	Q. We talked about that one.	24	of pelvic floor papers, but I did include
	Q. We talked about that one.		or pervie moor papers, out I did merade
	Page 287		Page 289
1	Page 287 What about any other studies?	1	Page 289 Richter's multi-center trial on Thomas that
1 2		1 2	
	What about any other studies?		Richter's multi-center trial on Thomas that
2	What about any other studies? I want to know other studies that you say you considered that were long-term follow-up, a year or more, for	2	Richter's multi-center trial on Thomas that was published in the New England Journal.
2 3	What about any other studies? I want to know other studies that you say you considered that were	2	Richter's multi-center trial on Thomas that was published in the New England Journal. Q. When you do an explant, does
2 3 4	What about any other studies? I want to know other studies that you say you considered that were long-term follow-up, a year or more, for	2 3 4	Richter's multi-center trial on Thomas that was published in the New England Journal. Q. When you do an explant, does your operative report record what specific
2 3 4 5	What about any other studies? I want to know other studies that you say you considered that were long-term follow-up, a year or more, for either Gynemesh® or TVT®, and you	2 3 4 5	Richter's multi-center trial on Thomas that was published in the New England Journal. Q. When you do an explant, does your operative report record what specific product it was?
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2 3 4 5 6 7 8 9	What about any other studies? I want to know other studies that you say you considered that were long-term follow-up, a year or more, for either Gynemesh® or TVT®, and you disregarded and you decided not to include them in your report.	2 3 4 5 6 7	Richter's multi-center trial on Thomas that was published in the New England Journal. Q. When you do an explant, does your operative report record what specific product it was? A. No. Q. Okay. It doesn't say TVT®
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	Page 290		Page 292
1	There's an education to these questions	1	Q. What's the author's name?
2	sometimes. So what I've tried not to do is	2	A. Last name is Mary, M-a-r-y.
3	throw companies or patients under the bus or	3	Q. Are you aware of any paper that
4	doctors in the I didn't mean patients	4	related to either TVT® or Gynemesh® PS or any
5	doctors or companies under the bus in my op	5	other type of sling or prolapse product that
6	notes. They're very bland. This is what I	6	says there's a chronic foreign body reaction
7	did; this is what I got out. The pathology	7	that produces chronic, long-term
8	report documents what I removed. I have the	8	inflammation?
9	implant log, I can go back and look it up,	9	A. Yes, Clavé paper.
10	but I will add more information to my op	10	Q. Anything else?
11	notes.	11	A. Not that I think of at this
12	Q. Is chronic inflammation more in	12	time.
13	the area of pathology than it is your area?	13	Q. Is the Clavé paper referenced
14	A. Chronic inflammation is a	14	in your report?
15	pathologic diagnosis, but it's manifested	15	A. I think it is.
16	with clinical symptoms.	16	
17	Q. You can have a chronic foreign	17	Q. Can you just let's just make that the last thing we do.
18	body reaction and not have any clinical	18	<u> </u>
19	symptoms, true?		Can you find your reference to
20	A. That's true.	19	the Clavé paper, please, in your report?
		20	Here it is. I don't believe
21	Q. Okay. In fact, it's not at all	21	it's based on my review, I don't believe
22	uncommon if people have a foreign body put in	22	it's in the Gynemesh® PS report.
23	their body permanently, then they often have	23	Well, I don't see it.
24	a permanent foreign body reaction, true?	24	Do you see it?
	Dago 201		
	Page 291		Page 293
1	A. No.	1	
1 2		1 2	
	A. No.		A. How could I forget to put that in there?
2	A. No.Q. Of some degree?A. Maybe of some degree, but not	2	A. How could I forget to put that in there? Q. Let's just get a final answer,
2	A. No.Q. Of some degree?	2	A. How could I forget to put that in there?Q. Let's just get a final answer, and I'll conclude the deposition.
2 3 4	A. No.Q. Of some degree?A. Maybe of some degree, but not of a large degree.Q. Right. That was my point.	2 3 4	A. How could I forget to put that in there? Q. Let's just get a final answer, and I'll conclude the deposition. MR. MATTHEWS: I've got a
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2 3 4 5 6	 A. No. Q. Of some degree? A. Maybe of some degree, but not of a large degree. Q. Right. That was my point. When you have a foreign body put in your body, you often the body often 	2 3 4 5 6	A. How could I forget to put that in there? Q. Let's just get a final answer, and I'll conclude the deposition. MR. MATTHEWS: I've got a couple questions. QUESTIONS BY MR. BALL:
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l	Page 294		Page 296
1	but the methodology is similar.	1	CERTIFICATE
2	Q. Explain what you mean.	2 3	I, CARRIE A. CAMPBELL, Registered
3	A. Well, you go through the		Merit Reporter, Certified Realtime Reporter
4	process of looking at papers and looking at	4	and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the
5	documents. What's different is that with the	5	examination, Dionysios K. Veronikis, M.D. was duly sworn by me to testify to the truth, the
6	Rule 26 report, I have corporate documents	6	whole truth and nothing but the truth.
7	and depositions and et cetera that you don't	7	I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the
8	normally have when you write a scientific	8	testimony as taken stenographically by and
9		9	before me at the time, place and on the date hereinbefore set forth, to the best of my
10	paper. On a scientific paper, you also	10	ability.
11	have research that you're conducting and		I DO FURTHER CERTIFY that I am
12	considering, but the actual methodology of,	11	neither a relative nor employee nor attorney nor counsel of any of the parties to this
13	you know, coming to a conclusion is the same;	12	action, and that I am neither a relative nor employee of such attorney or counsel, and
14	you take all of the data that's provided, and	13	that I am not financially interested in the
15	•	14	action.
16	you weigh in what you have at hand, and you come up with a decision.	15 16	
17	*		
18	Q. When you're doing a Rule 26 report, would I be correct that you're giving	17	CARRIE A. CAMPBELL, NCRA Registered Merit Reporter
19		18	Certified Realtime Reporter
	your professional opinion?	19	California Certified Shorthand Reporter #13921
20	A. Yes, it's my professional	20	Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter
21	opinion.		#084-004229
22	MR. MATTHEWS: I don't have	21	Texas Certified Shorthand Reporter #9328
23	another question, but I see Clavé on	22 23	Notary Public Dated: May 4, 2016
24	footnote 29 on the TVT®.	24	Dated. May 4, 2010
	Page 295		Page 297
1	MR. BALL: Well, let's look at	1	INSTRUCTIONS TO WITNESS
2	that.	2	
3	MR. MATTHEWS: It's actually	3	Please read your deposition over
4	referenced in an Ethicon document	4	carefully and make any necessary corrections.
5	that's cited in footnote 29. So it's	l _	
		5	You should state the reason in the
6	on page about the middle of	5	You should state the reason in the
6 7		1	•
	page 21.	6	You should state the reason in the appropriate space on the errata sheet for any corrections that are made.
7		6 7	You should state the reason in the appropriate space on the errata sheet for any
7 8	page 21. REDIRECT EXAMINATION.	6 7 8	You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing
7 8 9	page 21. REDIRECT EXAMINATION. QUESTIONS BY MR. BALL: Q. So just so we're clear, you	6 7 8 9	You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the
7 8 9 10	page 21. REDIRECT EXAMINATION. QUESTIONS BY MR. BALL: Q. So just so we're clear, you don't cite the Clavé paper or discuss the	6 7 8 9 10	You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to
7 8 9 10 11	page 21. REDIRECT EXAMINATION. QUESTIONS BY MR. BALL: Q. So just so we're clear, you	6 7 8 9 10 11 12	You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.
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